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## Improving neonatal resuscitation at birth : technique and devices

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## **Evaluating manual inflations during mask ventilation of preterm infants at birth**

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*Submitted*

## Abstract

### Objective

To evaluate sustained inflations (SIs) and consecutive inflations (CIs) during mask ventilation in preterm infants at birth by measuring mask leak, obstruction and expired tidal volume ( $V_{Te}$ ).

### Methods

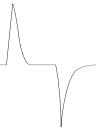
Airway pressures, gas flow, heart rate and oxygen saturation of infants < 32 weeks' gestation receiving mask ventilation with a T-piece were recorded. SIs and CIs during the first five minutes of respiratory support were analysed for mask leak, low  $V_{Te}$  (< 2.5 mL/kg), high  $V_{Te}$  (> 15 mL/kg in SIs, > 10 mL/kg in CIs) and airway obstruction.

### Results

In 27 infants (median (IQR) gestational age 29 (27–31) weeks), 1776 inflations were analysed. During SIs, mask leak was 80 (28–100) % and  $V_{Te}$  1.9 (0.0–5.9) mL/kg. During CIs mask leak was 34 (0–91) % and  $V_{Te}$  3.8 (1.4–6.7) mL/kg. Large mask leak (> 60%), low  $V_{Te}$ , high  $V_{Te}$  and airway obstruction per infant occurred in 67 (20–100) %, 40 (17–100) %, 0 (0–0) % and 0 (0–0) % of SIs and 44 (6–72) %, 35 (6–61) %, 3 (0–13) % and 3 (0–17) % of CIs, respectively. Heart rate increased quickly and 85% of infants were not intubated in the delivery room.

### Conclusion

We often observed large mask leak and low  $V_{Te}$ , especially during SIs. Despite this, most infants could be transported on CPAP.



## Introduction

Approximately 60% of preterm infants receive respiratory support at birth,<sup>1</sup> at which time adequate ventilation is crucial.<sup>2,3</sup> Immature lungs are highly susceptible to lung injury,<sup>4,5</sup> and there is increasing evidence that, when possible, intubation with mechanical ventilation should be avoided.<sup>6,7</sup>

Successful mask ventilation depends on good technique, avoiding large mask leak, airway obstruction, and inadequate tidal volumes. However, a large and variable leak between the mask and face often occurs with manikins<sup>8-11</sup> and infants,<sup>12,13</sup> even among experienced operators. This may lead to inadequate and uncontrolled tidal volume during PPV and result in ineffective ventilation and even lung injury.<sup>3-5,14-16</sup>

The problems of mask ventilation observed in our manikin studies, prompted us to evaluate mask ventilation in very preterm infants at birth. We performed a breath-by-breath analysis to evaluate how often mask ventilation was hampered by large face mask leak or airway obstruction, and how often this led to low or high tidal volumes. We also evaluated heart rate, oxygen saturation and the mode of ventilation when transported to the NICU.

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## Methods

This prospective observational study was performed in the neonatal intensive care unit (NICU) of the Leiden University Medical Center, a tertiary level perinatal care centre in Leiden, the Netherlands, with an average of 450 intensive care admissions per year.

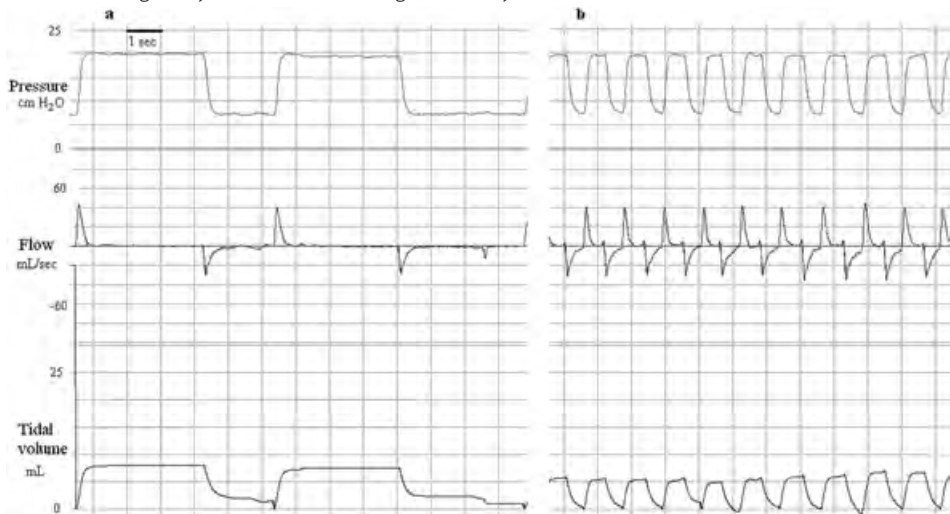
Recordings were made of infants with a gestational age < 32 weeks receiving PPV directly after birth via a facemask. We excluded infants who received CPAP only or no respiratory support, and infants who received PPV via nasopharyngeal tube. Both face mask and nasal tube are frequently used interfaces for PPV in the delivery room and an interface is chosen according to preference. Recordings for this study were made when time and logistics allowed the researchers to set up the equipment.

Resuscitation was performed by neonatologists, neonatal fellows or paediatric registrars using a T-piece infant resuscitator (Neopuff, Fisher & Paykel Healthcare, Auckland, New Zealand) with a round silicone face mask in the appropriate size for infant weight (Laerdal, Stavanger, Norway). Infants received heated and humidified gas (MR 850 heated humidifier and 900RD110 humidified resuscitation circuit, Fisher & Paykel Healthcare, Auckland, New Zealand). PPV was performed according to Dutch guidelines, starting with five SIs lasting 2–3 seconds, peak inspiratory pressure (PIP) 20 cm H<sub>2</sub>O, positive end expiratory pressure (PEEP) 5 cm H<sub>2</sub>O, gas flow rate 8 L/min and air.<sup>2,17</sup>

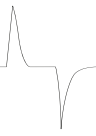
Respiratory interventions were recorded using a webcam and a Florian respiratory function monitor (Acutronic Medical Systems, AG, Switzerland), with a hot wire anemometer as flow sensor between the T-piece and facemask (dead space < 1 mL) to detect gas flow in and out of the mask. The flow signal was integrated to measure inspired and expired tidal volumes and the difference equals mask leak.<sup>8</sup> The monitor was always on to prevent electronic drift. The flow sensor was calibrated each time recordings were made. Pressure was measured from the distal section of the T-piece tubing. Using a respiratory monitor is in our local guidelines, if time allows it to be set up. The resuscitators were not blinded to the respiratory monitor but our experience is that they almost never looked carefully at the monitor during the resuscitation. The clinicians were not told by the research team what the monitor showed to minimise bias to the study.

Oxygen saturation and heart rate were measured with a Masimo SET pulse oximeter (Masimo Radical, Masimo Corporation, Irvine CA, USA). The monitor was turned on, the probe placed around the infant's right wrist and then attached to the monitor as soon as possible after birth.

Signals of gas flow, ventilatory pressure, tidal volume, oxygen saturation, heart rate and breathing were digitised and recorded at 200 Hz using Spectra physiological software (Grove Medical, London, UK). Using Spectra the signals for flow, pressure and volume were calibrated regularly before and during the study.

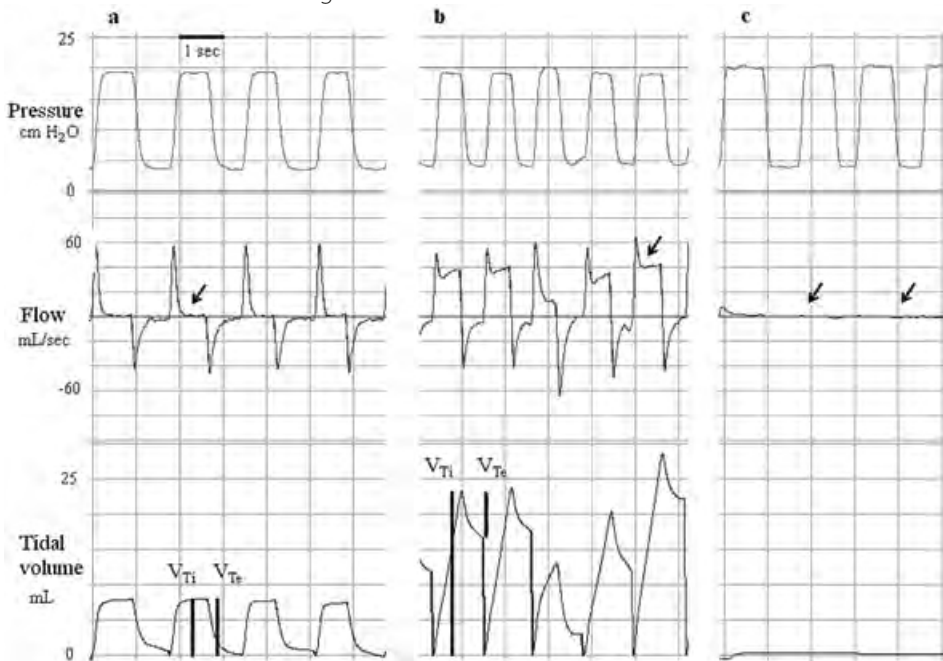


**Figure 1.** Two examples of inflations, characterised by an inspiratory flow simultaneous with an obvious increase in airway pressure from an inflation. The start of an expiratory flow was synchronous with the end of the inflation when airway pressure starts to return to the baseline pressure (a) A recording of two SIs. The first has a  $V_{te}$  of 7 mL/kg and mask leak of 22%, the second a  $V_{te}$  of 7.2 mL/kg and mask leak of 11%. (b) A recording of ten CIs. In these CIs  $V_{te}$  varies between 5–7 mL/kg and mask leak is minimal.



The inflations were divided into initial SIs and the following CIs. An SI was defined as a prolonged inflation given at the beginning of respiratory support in the delivery room. CIs were defined as inflations following SIs with a frequency of about 40–60 per minute (figure 1). All inflations during the first five minutes of mask ventilation after birth were carefully analysed on a breath-by-breath basis. We defined large mask leak as  $> 60\%$  as we found that above this level set pressures were often not reached and tidal volume decreased rapidly. We defined low expired tidal volume ( $V_{Te}$ ) as  $< 2.5$  mL/kg as this is close to dead space ventilation ( $\sim 2$  mL/kg). We defined high  $V_{Te}$  as  $> 15$  mL/kg in initial SIs and  $> 10$  mL/kg in CIs as  $V_{Te}$  is considered harmful when above this level.<sup>18,19</sup>

During neonatal resuscitation, airway obstruction may occur.<sup>9,12</sup> Obstruction could only be observed when leak was minimal, because large leak is a confounder to recognising airway obstruction.<sup>9</sup> Obstruction was calculated from inflations with  $< 30\%$  mask leak. We considered an inflation to be obstructed if there was a reduction in flow and volume, typical flattening of the flow waves when the PIP was unchanged ( $< 25^{\text{th}}$  percentile of mean  $V_{Te}$  per infant during inflations  $< 30\%$  leak was arbitrarily considered clinically significant airway obstruction). An example of a recording showing face mask leak and obstruction can be found in figure 2.



**Figure 2.** Three examples of recordings illustrating face mask leak and obstruction. (a) Minimal leak and no obstruction. Flow returns to zero (arrow) and inspired  $\approx$  expired tidal volume. (b) Large mask leak. Flow does not

return to zero (arrow) and  $V_{Te}$  is much smaller than inspired tidal volume. (c) Airway obstruction. Almost no inspiratory and expiratory flow waves are visible (arrows).  $V_{Te}$ : expired tidal volume,  $V_{Ti}$ : Inspired tidal volume.

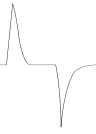
We recorded the mode of respiratory support (CPAP or intubation) infants received leaving the delivery room, whether infants were intubated within 24 hours, and morbidity and mortality before discharge. According to our local resuscitation guidelines intubation in the delivery room can be considered when: PPV is not effective (no increase in heart rate despite adequate ventilating technique) or breathing is absent and the infant is expected to require prolonged ventilation.

Data were analysed using SPSS (SPSS for windows, version 16.0, 2008, Chicago, IL). Results are presented as mean (standard deviation (SD)) or median (interquartile range (IQR)) where appropriate. To express the inter- and intra-individual variability we used the coefficient of variance (CV), calculated as  $(SD/mean) \times 100$  ( $< 10\%$  reflects acceptable agreement). To show correlations between continuous variables Pearson's correlation coefficient was used. To test for association between groups a Chi-square ( $\chi^2$ ) tests was used. The strength of the relationship between these variables was calculated with effect size Phi. A p-value  $< 0.05$  was considered statistically significant. Reported p values are two-sided.

The study was approved by the Institutional Review Board of the hospital. When possible, parental consent to record the resuscitation was obtained antenatally. Otherwise, a waiver of consent was used to record the resuscitation and parental consent to use the data was obtained afterwards.

## Results

From March 2009 to October 2010 we recorded 57 resuscitations of very preterm infants. Thirty of them were excluded because they did not meet the inclusion criteria for this study: in 14 infants (25%) a nasopharyngeal tube was used as interface, 8 received only CPAP and 3 infants did not require respiratory support. In 4 infants recordings were incomplete due to technical problems during the recordings and 1 infant had a gestational age  $> 32$  weeks. Thus, 27 infants were included in the study. The baseline characteristics of these infants are presented in table 1.

**Table 1.** Baseline characteristics of the infants

Infant characteristics (n=27)	
Birth weight (grams)*	1200 (985-1418)
Gestational age (weeks)*	29 (27-31)
Male gender†	14 (52%)
Caesarean section†	18 (67%)
Apgar score 1 min*	5 (3-6)
Apgar score 5 min*	7 (6-8)
Antenatal steroids†	17 (63%)

Data are presented as \* median (IQR) or † n (%)

## Inflations

A total of 3562 inflations and breaths were recorded, with a median (IQR) of 137 (86–172) per infant. A total of 1776 inflations were analysed (median (IQR) 57 (17–97) per infant), of which 124 were SIs and 1652 were CIs. Per infant we analysed 5 (4–6) SIs and 52 (12–92) CIs. PPV was started at 60 (32–81) seconds after birth and discontinued at 215 (135–363) seconds after birth.

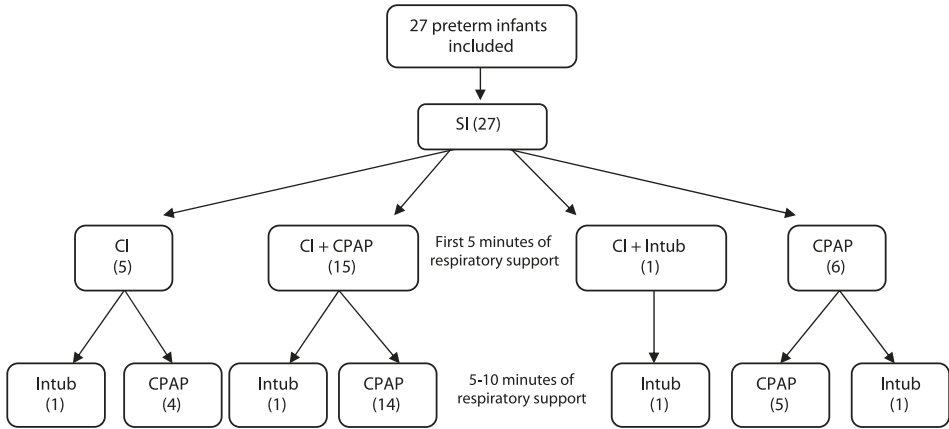
The remaining 1786 waveforms were spontaneous breaths (median (IQR) 47 (15–112) per infant). As evaluation of inflations was the subject of this part of the study, we excluded spontaneous breaths. Because of the extensive and detailed character of the analysis of breathing, this data will be reported in a companion chapter.

## Respiratory support, effect and outcome

All 27 infants received initial SIs. Subsequently, in 21/27 infants (77%) inflations were continued (CIs) and 6/27 infants (22%) received only CPAP after the SIs. The median (IQR) PIP was 20.6 (19.3–24.9) cm H<sub>2</sub>O and PEEP was 3.9 (3.2–4.6) cm H<sub>2</sub>O. In only 2/27 infants (7%) the PIP was increased by 5 cm H<sub>2</sub>O during the resuscitation.

In table 2 the Apgar score, heart rate and oxygen saturation in the minutes after birth are presented. All had an increase in heart rate when PPV was started and 75% of infants had a heart rate > 100/min at 3 minutes after birth. All infants were given extra oxygen within or at 5 minutes after birth because oxygen saturation was below the 25<sup>th</sup> percentile of target range at this time.<sup>20</sup> After starting oxygen supplementation, saturation increased rapidly in all infants and oxygen could be reduced to 21–30%. Four infants (15%) were intubated in the delivery room (figure 3).





**Figure 3.** Flow chart of early respiratory management in the delivery room. SIs: sustained inflations, CIs: consecutive inflations, CPAP: continuous positive airway pressure, Intub: intubation.

In total 11/27 (40%) of the infants were intubated within 24 hours of birth. The median (IQR) duration of mechanical ventilation was 2 (1–3) days. One infant (4%) developed a pneumothorax within 24 hours after birth. None of the infants died in the delivery room, 3/27 infants (11%) died during admission (in all three treatment was withdrawn within one week after birth because of poor prognosis, reasons: lung hypoplasia due to diaphragmatic hernia, multi-organ failure, severe neurological damage).

### Mask leak

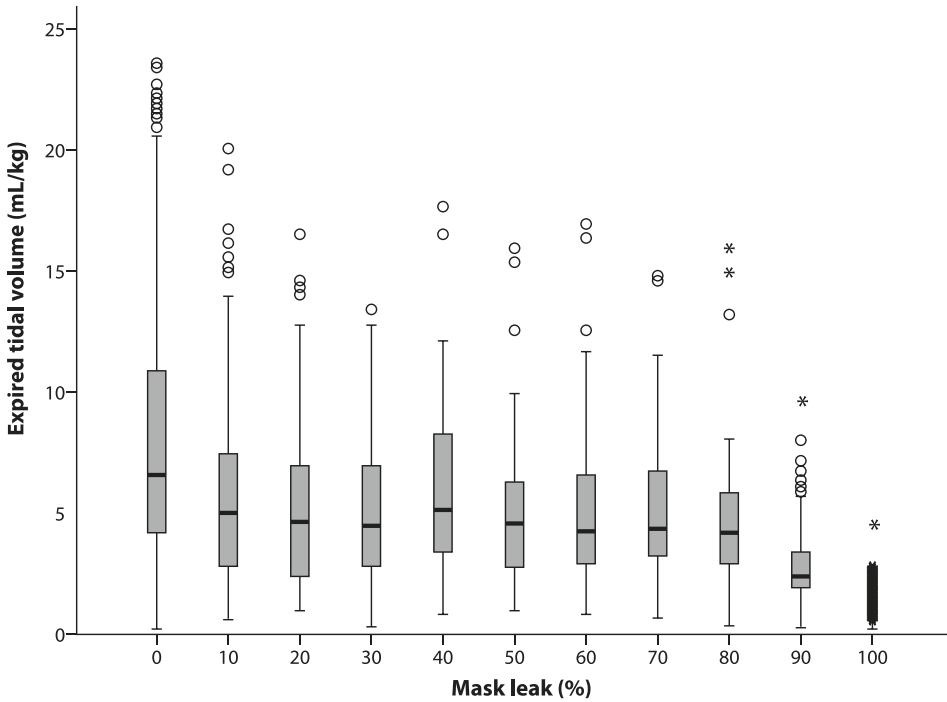
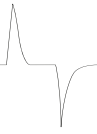
The median (IQR) percentage of mask leak in all inflations was 40 (0–92) %. The percentage of mask leak during SIs and CIs was 80 (28–100) % and 34 (0–91) %, respectively. Of all inflations, 42% (741/1776) showed mask leak > 60% (table 3).

**Table 2.** Apgar score, heart rate and oxygen saturation, if recorded

Apgar score, heart rate and oxygen saturation (n=27)				
	1 min	3 min	5 min	10 min
Apgar score	5 (3-6)	N/A	8 (6-8)	9 (8-9)
Heart rate (/min)	60 (49-111)	140 (103-154)	146 (110-164)	N/A
Oxygen saturation (%)	54 (41-64)	57 (45-66)	82 (53-90)	N/A

Data are presented as median (IQR). N/A = not available

There was a negative correlation between delivered  $V_{Te}$  and the percentage of mask leak (Pearson's correlation coefficient -0.58;  $p < 0.001$ ) (figure 4). During SIs mask leak was higher than during CIs, leading to lower tidal volumes during SIs. When mask leak was minimal (< 30% leak), the median (IQR)  $V_{Te}$  during SIs was 8.4 (4.0–10.5) mL/kg.



**Figure 4.**  $V_{Te}$  (mL/kg) vs. mask leak in groups: on the x-axis, 0% = inflations with 0–4% mask leak, 10% = 5–14%, etc. (100% comprises of inflations with 95–100% mask leak). The box plots show median values (solid black bar), IQR (margins of box), range, outliers (circles) and extreme values (asterisks).

### Expired tidal volume ( $V_{Te}$ )

The following median (IQR)  $V_{Te}$  were measured: all inflations 3.7 (1.1–6.7) mL/kg, SIs 1.9 (0.0–5.9) mL/kg and CIs 3.8 (1.4–6.7) mL/kg. There was a high variability in  $V_{Te}$  during PPV in each infant (intra-individual coefficient of variance 76%) and between infants (inter-individual coefficient of variance 62%). Low  $V_{Te}$  (< 2.5 mL/kg) was observed in 656/1776 inflations (37%). High  $V_{Te}$  (> 15 mL/kg) during SIs was observed in 1 infant during 1 inflation. High  $V_{Te}$  (> 10 mL/kg) during CIs occurred in 22/27 infants (81%) and 206/1652 inflations (12%) (table 3).

**Table 3.** Median (IQR) occurrence of large mask leak (> 60%), low expired tidal volume ( $V_{Te}$ ) (< 2.5 mL/kg), high  $V_{Te}$  (> 15 mL/kg in initial SIs, > 10 mL/kg in CIs) and airway obstruction during SIs and CIs per infant.

Effectiveness of mask ventilation		
	SIs (n=124)	CIs (n=1652)
Large leak (> 60%)	67 (20-100) %	44 (6-72) %
Low $V_{Te}$	40 (17-100) %	35 (6-61) %
High $V_{Te}$	0 (0-0) %	3 (0-13) %
Airway obstruction	0 (0-0) %*	3 (0-17) %**

SIs: Sustained inflations, CIs: Consecutive inflations, Large leak: > 60%, Low  $V_{Te}$ : < 2.5 mL/kg, High  $V_{Te}$ : SIs > 15 mL/kg, CIs > 10 mL/kg, Airway obstruction: < 25<sup>th</sup> percentile of measured  $V_{Te}$  in inflations with < 30% leak, \* n=33, \*\* n=804

### Airway obstruction

In 837/1776 inflations (47%) mask leak was < 30% and therefore this data could be used to assess obstruction reasonably accurately. During these inflations obstruction occurred in 20/27 infants (74%) and in 108/837 inflations (13%) (table 3).

### Intubation or CPAP

After initial ventilation, 4/27 infants (15%) were intubated before transport to the NICU. The other 23/27 infants (85%) were transported on CPAP.

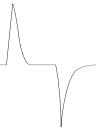
The occurrence of large mask leak (> 60%) during inflations was not significantly different between the intubated and CPAP group (39% vs. 42% of inflations;  $p = 0.307$ ). A significant difference was found between these groups in the occurrence of low  $V_{Te}$  (28% vs. 38%;  $p < 0.01$ ), but the effect was very small (effect size -0.07).

## Discussion

In this study, 1776 inflations of 27 very preterm infants were analysed in detail. Mask ventilation was frequently hampered by large mask leak leading to low  $V_{Te}$ . Airway obstruction or high  $V_{Te}$  occurred less often. However, in most infants heart rate increased and most infants were breathing on CPAP when transported to the NICU.

The optimal tidal volume during manual ventilation at birth is unknown, but usually targeted at 4–8 mL/kg,<sup>5</sup> which is in the range of tidal volumes of breathing infants and are below levels exceeding total lung capacity.<sup>5,18,19,21–24</sup> Although  $V_{Te}$  was frequently close to dead space ventilation, tidal volumes delivered during CIs in this study could be sufficient to resuscitate these infants since they were similar to tidal volumes of spontaneous breaths of preterm infants at birth.<sup>24,25</sup> Mask leak did not seem to influence the effect of resuscitation, but led to variable  $V_{Te}$ . Delivering consistent tidal volumes during PPV with a set pressure is difficult as lung compliance changes in the minutes after birth and compliance between infants varies.<sup>5</sup> Breathing during PPV adds to the large variation in tidal volume when using a set PIP.<sup>26</sup>

During SIs higher percentages of mask leak were observed than during CIs, leading to lower  $V_{Te}$ . It is likely that mask leak during SIs is higher because the mask is pressurised longer than during CIs. Large mask leak made it unlikely that the intended effect of the SIs, i.e. lung liquid clearance and creating functional residual capacity, was achieved. It is also possible that the length of the SI was insufficient as there are no studies available investigating repetitive SIs of 2–3 seconds. Experimental data showed that an inflation with an average of 14 seconds was needed for uniform lung aeration without causing overexpansion.<sup>27</sup> Clinical studies using SIs lasting 10–20 seconds in preterm infants at birth



showed a reduction in intubations.<sup>6,28,29</sup> Clinicians have been reluctant to use SIs because they are afraid injuriously high tidal volumes might occur. However, even for inflations with minimal mask leak, this did not occur.

Airway obstruction occurs frequently during mask PPV.<sup>9,12,30</sup> Studies use different definitions of obstruction. In our study, only inflations with < 30% leak were evaluated for obstruction in an attempt to minimise the confounding effect of leak. This could have led to an underestimation of its occurrence.

In most infants heart rate increased and pulse oxygen saturation climbed on the 25<sup>th</sup> centile line, consistent with the normal target ranges.<sup>20,31</sup> Almost all infants were transported to the NICU on CPAP with low oxygen need and only four infants needed to be intubated in the delivery room. In our study, the main reason for the clinicians to intubate was that they judged breathing to be absent. It is likely that breathing contributed to the ventilation. Evaluating breathing in detail is beyond the scope of this part of the study and will be addressed in a companion article.

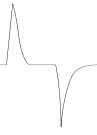
Using a respiratory function monitor is in our local guidelines and this might have influenced the performance of the clinicians. The monitor has not been used very often, as we just recently introduced it during resuscitation. We experienced that resuscitators hardly use the monitor for evaluation.

## **Conclusion**

This study shows that mask ventilation in preterm infants is often hampered by high and variable mask leak. As a result, tidal volumes are frequently low, especially during sustained inflations. However, in most infants heart rate increased quickly and oxygen saturation was restored. They could be transported to the NICU on CPAP. Potentially injurious high tidal volumes were seen when mask leak was low, but this did not occur often. Obstruction did occur and may have been underreported because of mask leak. It is possible that the tidal volumes delivered were sufficient or that manual ventilation initiated or was supported by breathing and influenced the effect of resuscitation.

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