Respiratory Function Monitor Guidance of Mask Ventilation in the Delivery Room: A Feasibility Study

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Objective To investigate whether using a respiratory function monitor (RFM) during mask resuscitation of preterm infants reduces face mask leak and improves tidal volume (V_T).

Study design Infants receiving mask resuscitation were randomized to have the display of an RFM (airway pressure, flow, and V_T waves) either visible or masked.

Result Twenty-six infants had the RFM visible, and 23 had the RFM masked. The median mask leak was 37% (IQR, 21%-54%) in the visible RFM group and 54% (IQR, 37%-82%) in the masked RFM group (P = .01). Mask repositioning was done in 19 infants (73%) of the visible group and in 6 infants (26%) of the masked group (P = .001). The median expired V_T was similar in the 2 groups. Oxygen was provided to 61% of the visible RFM group and 87% of the RFM masked group (P = .044). Continuous positive airway pressure use was greater in the visible RFM group (73% vs 43%; P = .035). Intubation in the delivery room was done in 21% of the visible group and in 57% of the masked group (P = .035).

Conclusion Using an RFM was associated with significantly less mask leak, more mask adjustments, and a lower rate of excessive V_T. *(J Pediatr 2012;160:377-81)*.

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International guidelines advocate positive-pressure ventilation (PPV) in a preterm infant who fails to breathe immediately after birth.[1] The purpose of PPV is to create a functional residual capacity, deliver an adequate tidal volume (V_T) to facilitate gas exchange, and stimulate breathing while minimizing lung injury.[2,3] A peak inflation pressure (PIP) is chosen during PPV with the assumption this will deliver an adequate V_T[1,4]; however, the V_T is rarely measured.[5,6] Low V_T may lead to inadequate ventilation, whereas excessive V_T may cause volutrauma. An observational study reported a mean V_T of 6.5 mL/kg in spontaneously breathing infants born at >29 weeks gestation in the first 90 seconds after birth.[7] Animal studies have shown that PPV with V_T >8 mL/kg can damage the lungs.[8-11]

Several factors can cause a leak between the mask and the infant's face and thus reduce the effectiveness of PPV. These include infant movements, movements of the operator's hand, or procedures such as fitting a hat.[6,12,13] A large face mask leak is a common, usually unrecognized, problem during resuscitation. Observational studies in the delivery room (DR) reported that resuscitators had mask leaks as high as 100%, and that most operators were unaware of the extent of the leaks.[5,6,13] Face mask leak results in loss of V_T passing through the mask. The best measure of the V_T delivered to the lungs is expired V_T (V_{Te}). In a large face mask leak, V_{Te} may be insufficient to achieve adequate gas exchange. Conversely, excessive V_{Te} may lead to hypocarbia and volutrauma may result.[14]

Kattwinkel et al[15] showed resuscitators respond faster to compliance changes if V_T rather than pressure is displayed. We have demonstrated that the use of a respiratory function monitor (RFM) can guide PPV in the DR.[14] A display of flow, V_T, pressure wave, and mask leak data during PPV can allow the clinical team to quickly recognize mask leak, inadequate V_T, or airway obstruction[13,16,17] and then adjust

CPAP	Continuous positive airway pressure
DR	Delivery room
NICU	Neonatal intensive care unit
PEEP	Positive end-expiratory pressure
PIP	Peak inflation pressure
PPV	Positive-pressure ventilation
RFM	Respiratory function monitor
V_T	Tidal volume
V_{Te}	Expired tidal volume

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the mask hold, position, or airway pressure to deliver safe and effective V_T.[14] The display also shows the infant's breathing pattern[18,19] and identifies asynchrony with inflations.[20]

Ventilation with targeted V_T to minimize lung damage and avoid hypercarbia and hypocarbia is accepted ventilator management in many neonatal intensive care units (NICUs).[21] Clinicians are increasingly realizing the importance of optimizing respiratory management of preterm infants from the first minutes of life.[22-24] Thus, we sought to examine whether the use of an RFM led to improved mask ventilation in the DR. We hypothesized that continuous display of data on mask leak and delivered V_T during PPV will lead to a reduction in mask leak and improved V_T delivery.

Methods

All infants were born at The Royal Women's Hospital, Melbourne, Australia, a tertiary perinatal center where ~6000 infants are delivered and more than 100 infants with birth weight <1000 g are admitted to the NICU annually. The trial was conducted between November 2008 and January 2010. Infants who were <32 weeks postmenstrual age and deemed to have inadequate breathing after birth were eligible. Exclusion criteria included undocumented gestational age and a congenital abnormality that could adversely affect breathing. The trial was approved by The Royal Women's Hospital Research and Ethics Committees and was registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12608000357358).

Infants were randomly allocated to either have the screen of an RFM visible (RFM visible group) or covered (RFM masked group). Allocation was block-randomized with various-sized blocks (4-8). A sequentially numbered, sealed, opaque envelope containing the allocation was opened just before the birth of an eligible infant. Twins and triplets were randomized as individuals.[25]

Consent was obtained before birth if the mother was not in established labor and if time permitted. Where this was not possible, retrospective consent was obtained in accordance with Australian National Health and Medical Research Council guidelines for studies in emergency medicine.[26] Consent to use the data was then sought as soon as possible after the birth.

Ventilation Device and Face Mask

Infants received mask PPV with a size 00 round silicone face mask (Laerdal, Stavanger, Norway) connected to a T-piece device (Neopuff Infant Resuscitator; Fisher & Paykel Healthcare, Auckland, New Zealand), a continuous-flow, peak pressure-limited device with a manometer and a positive end-expiratory pressure (PEEP) valve. All participating clinicians were trained in the use of the device.

Respiratory Function Monitor

A hot-wire anemometer flow sensor (Florian Respiratory Function Monitor; Acutronic Medical Systems, Zug, Switzerland) was placed between the ventilation device and the face mask to measure and display gas flow, V_T, and airway pressure. V_T and V_{Te} were automatically calculated by integrating the flow signal. Staff members attending deliveries were trained to interpret these signals using a mannequin. Before each delivery staff received a brief refresher on interpreting the display waves.

Resuscitation Procedures

The resuscitation team typically comprised a neonatal nurse, a pediatric resident, a neonatal fellow, and a neonatal consultant. The resident performed the mask ventilation. In the RFM visible group, the resuscitation team were instructed to observe gas flow waves to identify mask leak and to adjust the mask position or PIP as necessary. Resuscitation was started with air. If the infant had an oxygen saturation of <70% at 5 minutes after birth or <90% at 10 minutes after birth or required chest compressions at any time, then the fraction of inspired O_2 was increased to 100% to achieve an oxygen saturation in accordance with published nomograms.[27]

Immediately after birth, the infant was placed in a polyethylene bag under radiant heat. The clinical team determined whether to provide PPV or continuous positive airway pressure (CPAP). The initial CPAP setting was 5 cm H_2O and was increased up to 8 cm H_2O if the infant was breathing regularly with signs of respiratory distress (eg, expiratory grunt, chest recession). Infants who required PPV were ventilated with an initial PIP of 30 cm H_2O, a PEEP of 5 cm H_2O, a gas flow of 8 L/min, and an inflation rate of 40-60/min. In the RFM masked group, resuscitators used clinical assessment of chest rise to guide ventilation. In the RFM visible group, resuscitators could also use the displayed V_{Te} to attempt to maintain a V_{Te} of 4-8 mL/kg. Intubation criteria were defined a priori as fraction of inspired O_2 >40% with CPAP of 8 cm H_2O, no increase in heart rate despite adequate mask ventilation for 60 seconds, apnea, and chest compressions. Other resuscitative measures (eg, cardiac massage, drugs) were provided at the discretion of the clinical team, in accordance with 2005 Australian guidelines for neonatal resuscitation.[28]

Sample Size and Power Estimates

The primary outcome measure was mask leak during PPV. Our previous data showed a mean mask leak of 45% ± 20%. We hypothesized that the RFM visible group would have a lower mean mask leak. A sample size of 56 (28 in each group) was sufficient to detect a clinically important (15%) reduction in mask leak from 45% to 30%, with 80% power and a 2-tailed α error of 0.05.

Data Collection and Analysis

Demographic data were recorded for all study infants. Only infants who received more than 40 inflations during PPV were included in the analysis. Analysis was performed manually for the first 40 inflations in each infant. PIP, PEEP, V_{Te}, inflation time, ventilation rate, and minute ventilation were measured. We calculated the percentage of face mask leak using the following formula: [(inspiratory V_T − expiratory V_T)