Suction Mask vs Conventional Mask Ventilation in Term and Near-Term Infants in the Delivery Room: A Randomized Controlled Trial

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Objective To compare the suction mask, a new facemask that uses suction to create a seal between the mask and the infant's face, with a conventional soft, round silicone mask during positive pressure ventilation (PPV) in the delivery room in newborn infants >34 weeks of gestation.

Study design Single-center randomized controlled trial in the delivery room. The primary outcome was mask leak.

Results Forty-five infants were studied at a median gestational age of 38.1 weeks (IQR, 36.4-39.0 weeks); 22 were randomized to the suction mask and 23 to the conventional mask. The suction mask did not reduce mask leak (49.9%; IQR, 11.0%-92.7%) compared with the conventional mask (30.5%; IQR, 10.6%-48.8%; $P = .51$). The suction mask delivered lower peak inspiratory pressure (27.2 cm H_2O [IQR, 25.0-28.7 cm H_2O] vs 30.4 cm H_2O [IQR, 29.4-32.5 cm H_2O]; $P < .05$) and lower positive end expiratory pressure (3.7 cm H_2O [IQR, 3.1-4.5 cm H_2O] vs 5.1 cm H_2O [IQR, 4.2-5.7 cm H_2O]; $P < .05$). There was no difference in the duration of PPV or rates of intubation or admission to the neonatal intensive care unit. In 5 infants (23%), the clinician switched from the suction to the conventional mask, 2 owing to intermittently low peak inspiratory pressure, 2 owing to failure to respond to PPV, and 1 owing to marked facial bruising after 6 minutes of PPV.

Conclusions The use of the suction mask to provide PPV in newborn infants did not reduce facemask leak. Adverse effects such as the inability to achieve the set pressures and transient skin discoloration are concerning. *(J Pediatr 2018;■■:■■-■■).*

Trial registration Australian and New Zealand Clinical Trial Registry ACTRN12616000768493.

Neonatal resuscitation guidelines recommend providing positive pressure ventilation (PPV) in the delivery room to infants who do not establish effective spontaneous breathing.[1] This measure is needed in approximately 10% of newborn infants.[2] For these infants, PPV aims to facilitate aeration of the lung by providing adequate tidal volume (V_t) until the infant establishes regular spontaneous breathing.[3] However, mask ventilation can be challenging because of air leak around the mask.[4,5] Other devices, such as a nasal tube[6] or a laryngeal mask[7] are available, but the soft silicone round facemask is the most commonly used interface for newborns. Leak can be measured using a respiratory function monitor and is frequently reported as an outcome in clinical trials evaluating the effectiveness of ventilation of newly born infants.[4,5,8-10]

A new facemask uses suction to create a seal between the mask and the infant's face. In a manikin model, this facemask reduced leak by 95% compared with a conventional mask.[11] Our aim was to compare the suction mask with a conventional mask during PPV in newborn infants after birth.

Methods

This single-center, randomized controlled trial was carried out at The Royal Women's Hospital, Melbourne, Australia. The Royal Women's Hospital Human Research and Ethics Committee approved retrospective parental consent in line with National Health and Medical Research Council guidelines.[12] Written parental consent was sought as soon as possible after randomization. The study was registered with the Australian and New Zealand Clinical Trial Registry (ACTRN12616000768493).

PEEP	Positive end-expiratory pressure
PIP	Peak inspiratory pressure
PPV	Positive pressure ventilation
V_t	Tidal volume

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LSR Healthcare provided the suction masks for the study. The company had no involvement in the study design, data collection or interpretation, or the decision to present or publish the results. Funded by the NHMRC Program Grant 2017-2021 (App 1113902), (App ID 1059111 [to P.G]), (App ID 1073533 [to O.K.]), (App ID 1097089 [to L.O.]), and (App ID 1111134 [to M.T.]). L.L. received a research fellowship from the German Research Society (DFG-grant LO 2162/1-1) and intramural TÜFF Habilitation Program (TÜFF [2459-0-0]). C.R. received an early Postdoc Mobility fellowship from the Swiss National Science Foundation (P2ZHP3_161749). The authors declare no conflicts of interest.

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Patients, Recruitment, Randomization, and Study Intervention

Infants were eligible if they were born at ≥34 weeks of gestation and were included in the study if they received ≥5 PPV inflations at birth. Infants with congenital facial anomalies were excluded.

Pediatric trainees resuscitated infants at high-risk deliveries according to international neonatal resuscitation guidelines.[1] Before the commencement of PPV, the attending researcher opened a sequentially numbered, sealed, opaque envelope, and infants were randomly assigned to receive PPV with either the suction mask or the conventional mask (**Figure 1**). A computer-generated randomization sequence with variable block sizes was used. The clinician was informed by the researcher that an adequate seal using the suction mask was achieved when the indicator arrow on the suction gauge rose, along with a corresponding change in the sound of the suction.

Changing to the standard conventional mask was permitted if the suction mask was judged to be ineffective by the pediatric trainee. In these cases, primary and secondary outcomes were assessed until the masks were switched. Blinding to the intervention was not possible, but the clinical team was blinded to the respiratory function monitor data.

Outcomes and Sample Size

The primary outcome was reported as the median leak during PPV. Secondary outcomes were peak inspiratory pressure (PIP; in cm H_2O), positive end-expiratory pressure (PEEP; in cm H_2O), V_t (in mL/kg), number of inflations provided, infant heart rate (in bpm), and oxygen saturation (%), fraction of inspired oxygen, Apgar score, duration of PPV (seconds), rates of intubation, admission to neonatal intensive care unit, number of mask repositions, use of an alternative mask, and skin trauma.

The sample size was based on a study in preterm infants in the delivery room in which the mean ± SD facemask leak was 30% ± 17%.[5] In a manikin model, we reported a 95% decrease in leak using the suction mask compared with a conventional mask.[11] To achieve a more conservative 50% decrease in leak from 30% using the conventional mask, to 15% using the suction mask, with 80% power and 2-tailed alpha error of 0.05, 44 infants (22 in each group) were needed. Recruitment continued until 44 infants receiving ≥5 PPV inflations were recruited.

Equipment and Analysis

The conventional mask (Laerdal Silicone mask, Laerdal, Stavanger, Norway) used in the study was a size 0/1, silicone, round facemask. The suction mask (ResusiSure, LSR Health care, NSW, Australia) has a side port to connect a suction tube (75 mm Hg negative pressure) to form a vacuum between the inner and outer rims of the mask (**Figure 1**).

A Neopuff Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand) was used to provide positive pressure with initial settings of PIP of 30 cm H_2O, PEEP of 5 cm H_2O, and fraction of inspired oxygen of 0.21.

Airway flow and pressure were measured using a small (dead space 0.7 mL) sensor with an accuracy of ±5% placed between the Neopuff and the mask.[13] This signal was automatically integrated to provide inspired and expired V_t. Respiratory function measures were recorded at 200 Hz using the New Life Box physiological recording system (Advanced Life Diagnostics UG, Weener, Germany). Heart rate and oxygen saturation were measured using a pulse oximeter (Masimo Radical 7; Masimo Cor-

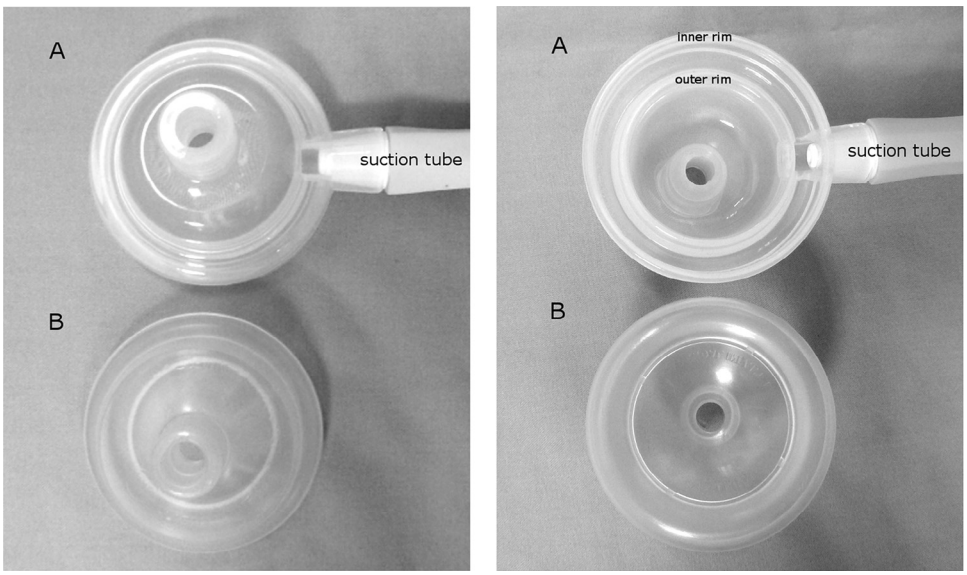

Figure 1. Suction mask (**A,** ResusciSure mask—outer diameter 60 mm, inner diameter 40 mm) and the conventional mask (**B,** Laerdal mask size 0/1—outer diameter = 60 mm, inner diameter = 40 mm) viewed from top (left photo) and from bottom (right photo) of the mask.

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