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Clinical paper

# Smaller facemasks for positive pressure ventilation in preterm infants: A randomised trial

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## Abstract

**Aim:** Facial measurements of preterm infants indicate that standard diameter facemasks used during positive pressure ventilation are too large, which may lead to mask leak and compromise resuscitation. We aimed to determine whether the use of a facemask that better complies with the dimensions of preterm faces, compared with a standard facemask, reduces facemask leak.

**Methods:** Parallel group, randomised controlled trial. Preterm infants ≤32 weeks' gestation receiving facemask ventilation prior to intubation in the neonatal intensive care unit, and those 28–$32^{+6}$ weeks' receiving facemask ventilation in the delivery room were eligible. Infants were randomised to receive ventilation via a standard (50 mm) (control), or a smaller (35 mm or 42 mm) diameter facemask (intervention), stratified by gestation (≤26 weeks'; 35 mm, 27–$32^{+6}$; 42 mm). The primary outcome was leak between the mask and the infants face.

**Results:** Of 298 eligible infants, 139 were randomised and 131 were included in the final analysis; 66 in the intervention group and 65 in the control group. The median (IQR) leak was 42% (13–69%) in the intervention group compared with 39% (22–66%) in the control group $P = 0.43$. The median (IQR) lowest oxygen saturation was similar in both groups [intervention 70% (34–93%) vs. control 71% (40–93%) $P = 0.75$]. One infant crossed over from the intervention to the control group due to poor response to ventilation with the intervention facemask.

**Conclusions:** Smaller facemasks did not reduce mask leak in preterm facemask ventilation. All facemasks had high leak, particularly in infants ≤26 weeks' gestation.

**Clinical trial registration:** This trial is registered with the Australian New Zealand Clinical Trials Registry, ACTRN12614000709640, www.anzctr.org.au.

**Keywords:** Newborn, Neonate, Infant, Resuscitation, Mask, Facemask, Positive pressure ventilation, Respiratory function monitor

*Abbreviations:* IQR, interquartile range; VT, tidal volume; PPV, positive pressure ventilation.

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## Introduction

Aeration of the newborn lung is the critical event underpinning the pulmonary and cardiovascular transition to extra uterine life.[1] If effective spontaneous breathing does not occur soon after birth, international resuscitation guidelines recommend that respiratory support be provided.[2] Respiratory support is administered to approximately 10% of newborns[3] and is typically delivered using a pressure delivery device attached to a facemask.[4] It is important that applied pressure is delivered effectively and accurately, as both over or under ventilation can cause harm, particularly to the preterm lung.[5] Delivering effective newborn facemask ventilation is challenging and is frequently compromised by leak around the facemask, airway obstruction, or a combination.[6,7] Facemask leak of up to 54% has been reported[8–10] during mask ventilation of preterm infants, yet clinicians are frequently unaware of the problem.[11] Neonatal resuscitation training programs (Neonatal Resuscitation Program, Newborn Life Support, Australian and New Zealand Council on Resuscitation)[12–14] recommend the use of a mask that covers the nose and mouth, but that does not overlap the eyes or chin. However, specific facemask measurements for use in preterm infants are not suggested.

Thus far there has been little evidence to guide the choice of mask in preterm infants, and the smallest sized standard facemasks used in our institution have an external diameter of 50mm. O'Shea et al. published measurements of preterm infants' faces suggesting that the 50mm facemasks may not conform to international guidelines on mask size.[15] Smaller facemasks, with diameters of 35mm and 42mm are available, which may comply more closely with resuscitation recommendations.[15] The objective of this study was to assess the facemask leak when using smaller facemasks (35mm or 42mm) compared with the standard mask (50mm) while delivering positive pressure ventilation (PPV) to preterm infants.

## Methods

### Trial design

This was a single centre, stratified, parallel-group randomised controlled clinical trial conducted at the Royal Women's Hospital, Melbourne, Australia. This institution is a tertiary perinatal referral centre catering for >7500 deliveries per year.[16] Written parental consent was obtained either prospectively, or as soon as possible after randomisation. The Royal Women's Hospital Research and Ethics Department approved the project and retrospective parental consent, in accordance with National Health and Medical Research Council guidelines.[17] Eligibility was initially restricted to those receiving PPV before intubation in the neonatal intensive care unit. To improve the rate of recruitment and the generalizability of results, eligibility criteria were expanded on the 25th October 2017 to include infants receiving PPV in the delivery room.

### Participants

Eligible infants were those ≤32 weeks' corrected gestational age who required PPV via a facemask before intubation with sedation and muscle relaxation in the NICU, or infants $28^{+0}$ to $32^{+6}$ weeks' gestation who required PPV in the delivery room or operating theatre immediately after birth, who did not receive sedation or muscle relaxation. Exclusion criteria were infants who did not receive PPV prior to intubation, those who had a congenital anomaly of the face or newly born infants ≤27 weeks' gestation, as they were eligible for a conflicting and preceding delivery room study which required that respiratory data was unblinded during facemask ventilation. Each infant could only be randomised once, regardless of the number of intubations.

### Interventions

Eligible participants were randomly assigned to receive facemask ventilation with either a standard (50mm) or smaller (35mm or 42mm) diameter mask. Infants were stratified by corrected gestational age at the time of PPV episode, ≤26 weeks' gestation were allocated the 35mm facemask (Fisher & Paykel Healthcare, Auckland, New Zealand) and those $27^{+0}$ to $32^{+6}$ weeks' gestation allocated the 42mm facemask (Fisher & Paykel Healthcare, Auckland, New Zealand). These groups were based on published measurements of preterm infant faces.[15] Infants in the control group were assigned the standard 50mm diameter facemask (Laerdal Silicone facemask size 0/0, Laerdal, Stavanger, Norway). All masks were soft silicone round masks. PPV was delivered by a paediatric doctor (resident, registrar, fellow or consultant). All doctors were taught the facemask holds and placement techniques described by Wood et al.[18,19]

### Equipment

Facemask ventilation was administered using the Neopuff Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand), a pressure limited T-piece device. The initial settings used were a gas flow of 10L/min, a peak inspiratory pressure of 25cm $H_2O$, a positive end expiratory pressure of 5cm $H_2O$ and a fraction of inspired oxygen of 0.3 in the delivery room. A dual-hotwire-anemometer flow sensor was inserted between the facemask and T-piece. A Florian respiratory function monitor (Acutronic Medical Systems, Ag, Switzerland) measured gas flow and pressure. Flow measurements were integrated to provide the tidal volume. Pressure was measured through a pressure line connected to the T-piece circuit. Respiratory data were recorded using Spectra software (Grove Medical, London, UK) or the New Life Box physiological recording system (Advanced Life Diagnostics UG, Weener, Germany) in the delivery room. Heart rate and oxygen saturation were recorded using a pulse oximeter (Masimo Radical 7; Masimo Corporation, Irvine California), with 2-s averaging, and the fraction of inspired oxygen was measured using a Teledyne oxygen analyser (Teledyne Analytical Instruments, City of Industry, CA, USA) inserted into the inspiratory limb of the T-piece circuit. Video recordings were made of all episodes of facemask ventilation using an angled webcam (Logitech).

### Respiratory analysis

Facemask leak was defined as the difference between inspiratory and expiratory tidal volume (VT), expressed as a percentage of inspiratory VT.[20] Respiratory waves were analysed inflation to inflation by a single researcher (EOC) using Spectra software, blinded to the video input, case report forms and group allocation. An obstructed inflation was defined as one with an expiratory VT of <2.4ml/kg i.e. <60% of the minimum tidal volume (4 ml/kg), as previously described.[11] For each individual participant, mean/median respiratory data was calculated for all inflations without obstruction. These individual participant means/medians values were then analysed as continuous data in each randomisation group. Spontaneous breaths between PPV inflations were not analysed. If more than one episode of PPV was required i.e. between intubation attempts, only the first two attempts were analysed.

### *Outcome measures*

The primary outcome measure was leak between the facemask and the infant's face during PPV. Facemask leak was compared between the control and intervention groups. Secondary outcomes included respiratory outcomes such as the expiratory VT, percentage of obstructed breaths, the highest fraction of inspired oxygen, peak inspiratory pressure, duration of PPV and attempts at repositioning of the mask. Secondary outcomes included clinical data, the infant's lowest heart rate and lowest oxygen saturation during mask ventilation. Facemask leak was selected as a primary outcome as it is an objective, quantifiable measure of mask function that has commonly been reported in many studies of newborn resuscitation devices.[8–10,21,22]

### *Sample size*

Facemask leak between 29% and 54% has previously been reported during preterm mask ventilation.[8–10] A leak of 50% in the control group was therefore assumed. To detect a clinically significant 15% absolute difference in leak between the groups (50% versus 35%), with a power of 80% and a 2-tailed alpha error of 0.05, a sample size of 128 (64 in each arm) was calculated. An interim analysis for safety was conducted by an independent clinician at the midpoint of the trial (data from the first 60 enrolled infants) and continuation of recruitment was recommended.

### *Randomisation*

Computer-generated block randomisation using variable block sizes was produced, independent of the study team. Participants were allocated individually using sequentially numbered, sealed, opaque envelopes containing the group allocation. Randomisation occurred in three strata; in the neonatal intensive care unit with a corrected gestation of ≤26 weeks', in the neonatal intensive care unit with a corrected gestation of $27^{+0}$ to $32^{+6}$ weeks' or in the delivery room with a gestation of $28^{+0}$ to $32^{+6}$ weeks'.

### *Blinding*

Clinicians administering PPV were not blinded to the group allocation, however they were blinded to the respiratory function monitor waveforms and were not provided information on facemask leak or tidal volume delivery by the researcher. Outcome assessors and data analysts were blinded to the group allocation.

### *Statistical methods*

Continuous data for each infant were summarized as a mean (standard deviation) if normally distributed, or as a median (interquartile range [IQR]) if the distribution was skewed. Outcome variables were analysed using the Student t test for parametric and Mann–Whitney U test for nonparametric comparisons. Differences of means and 95% confidence intervals were estimated using the Student t-test and differences of medians and 95% confidence intervals were estimated using quantile regression analysis. Categorical variables, summarized as numbers and percentages, were analysed using the Chi-square test. An intention to treat analysis was performed. Data analysis was undertaken with Stata software (Intercooled V.14, Stata Corp, College Station, Texas, USA).

## Results

Participants were recruited from September 2014 to February 2018. Of 298 eligible infants, 139 (47%) were randomised with 131 included in the final analysis, 66 in the intervention group and 65 in the control group (Fig. 1). Demographic data were similar in both groups (Table 1). Operator role and experience were equivalent in both groups (Table 2). The smaller facemasks did not reduce leak; median (IQR) facemask leak was 42% (13–69%) in the smaller facemask group compared with 39% (22–66%) in the control group, difference in medians 4 (confidence interval −11 to 20), $P=0.43$ (Fig. 2). There were no differences in important secondary outcomes including the expiratory tidal volume, positive end expiratory pressure or percentage of obstructed breaths. There were no differences in physiological stability including lowest oxygen saturation or heart rate during PPV (Table 3). The median (IQR) lowest oxygen saturation during facemask ventilation was 71% (40–93%) in the standard mask group and 70% (34–93%) in the smaller mask group. One infant crossed over from the intervention to the control 'standard' mask group due to a 'failure to respond' to PPV. An exploratory subgroup analysis revealed that there was no difference in the mask leak between the standard or smaller mask groups in infants ≤26 weeks' [mean (SD), 60% (32%) vs. 51% (28%) $P=0.44$], or in those $27^{+0}$ to $32^{+6}$ weeks' median (IQR), 38% (18–62%) vs. 34% (11–65%) $P=0.59$] (Table 4).

## Discussion

### *Brief synopsis of key findings*

We found that administering facemask ventilation to preterm infants via a smaller diameter facemask compared with the standard larger diameter facemask did not reduce facemask leak. High facemask leak was found in preterm infants ≤26 weeks' gestation, irrespective of the facemask used. Whilst there were no differences in physiological measurements between the groups, the median lowest oxygen saturation during PPV of 70% and 71%, were substantially below our institution's target range of 91–95%, although an adequate heart rate of over 100 beats per minute was maintained in both groups.

### *Possible mechanisms and explanations*

Despite evidence that smaller facemasks more closely conformed to the measurement of preterm infants faces and to international resuscitation recommendations for mask placement,[15] their use in this study did not translate into an objective reduction in facemask leak. The degree of facemask leak and low oxygenation saturations observed in this study are comparable to previous reports, suggesting

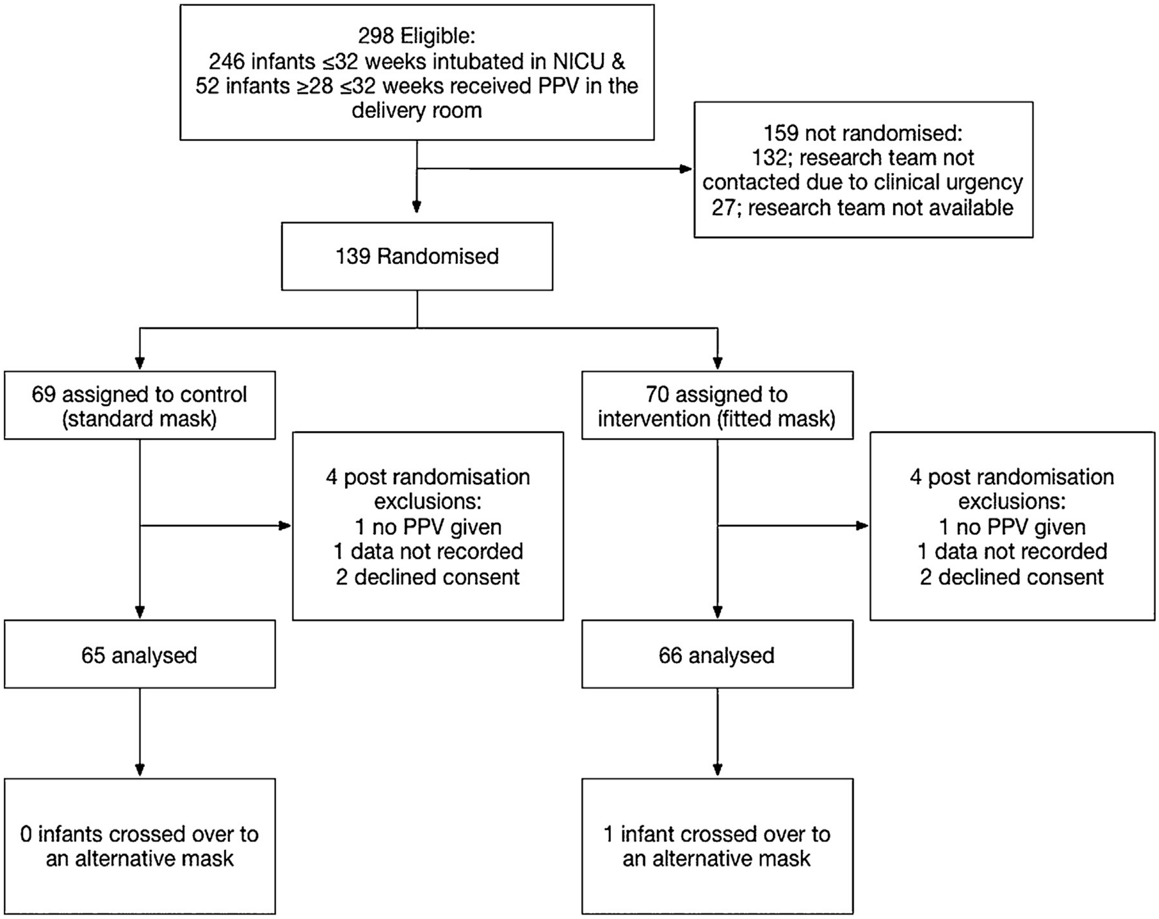


**Fig. 1 – CONSORT flow diagram.**
**Legend: Participant recruitment.**

that current equipment and techniques for providing PPV for preterm infants could be improved. High facemask leak was observed in infants ≤26 weeks' gestation.

Equipment or operator factors such as facemask placement, mask characteristics (shape, size, material), facemask hold, or a combination of these factors may explain the high leak observed with the smaller mask. We hypothesise that despite the smaller facemask size, the operator may fail to place the mask correctly, in accordance with international resuscitation guidelines. The distance of a preterm infant's naso-frontal groove to their mental protuberance ranges from 32 mm to 35 mm[15] at <26 weeks' gestation. A 35 mm mask must be placed within a small area with little margin for error and we suggest that this is difficult to achieve and may result in increased mask leak. While the smaller mask may have been the correct size, other mask characteristics such as shape,[23] rim[24] and malleability have also been shown to influence ventilation quality.[19] The smaller facemasks may have been vulnerable to distortion, possibly increasing mask leak. Factors outside of the facemask's dimensions may also account for the leak observed. Different facemask holds have been found to influence leak[25] and this is a poorly reported confounder in studies of resuscitation equipment. A strength of our study is that the mask hold was reported and was equivalent in both groups. Emerging evidence from animal studies also indicates that closure of the epiglottis and larynx may impede effective ventilation, and warrants further study.[26] Newly developed facemasks have shown promise in manikin studies,[24] but this has not consistently translated into the clinical environment,[27] emphasising the challenges in developing superior facemasks. While single nasal prongs have not been shown to be superior to facemasks,[28] alternative pressure delivery systems[29] or alternative interfaces to deliver PPV, such as laryngeal mask airways[30] or nasal interfaces warrant continuing investigation.

Expired tidal volume recorded in this study (9.7–12.6 ml/kg) was higher than the suggested range in mechanically ventilated preterm infants (4–6 ml/kg).[31] There is little evidence to guide tidal volume delivery during PPV in preterm infants prior to intubation in the neonatal intensive care setting. Other studies of preterm PPV in the delivery room have reported expired tidal volumes of 5.7–8.7 ml/kg.[6,8–10] During PPV, tidal volume is proportional to peak inspiratory pressure and lung compliance.[32] Although lung compliance was not measured in this study, we hypothesise that these infants had a higher lung compliance than those in the delivery room and that the peak inspiratory pressure of 25 cm $H_2O$ used in the study therefore resulted in higher tidal volumes than expected, despite the leak observed. Though high leak could protect against high tidal volumes in the setting of inappropriately high peak inspiratory pressures, both the leak and tidal volume delivered were highly

**Table 1 – Demographics.**

| | Standard mask n=65 | Smaller mask n=66 |
|---|---|---|
| Birthweight (g), mean (SD) | 1033 (370) | 1041 (351) |
| Gestational age (weeks), mean (SD) | 27 (2.2) | 27 (2.1) |
| Age when studied (hours), median (IQR) | 27 (8–147) | 34 (9–194) |
| Weight when studied (g), mean (SD) | 1079 (343) | 1085 (337) |
| Corrected gestation (weeks), mean (SD) | 28 (1.7) | 28 (1.8) |
| Male, n (%) | 44 (68) | 35 (53) |
| Caesarean section, n (%) | 47 (72) | 49 (74) |
| General anaesthesia, n (%) | 8 (12) | 10 (15) |
| Apgar score at 5 min, median (IQR) | 8 (7–9) | 8 (7–9) |
| Indication for mask ventilation, n (%): | | |
| Intubation | 60 (92) | 63 (95) |
| Delivery room resuscitation | 5 (8) | 3 (5) |
| Indication for intubation, n (%): | | |
| Respiratory failure | 49 (82) | 48 (76) |
| Apnoea | 9 (15) | 10 (16) |
| Endotracheal tube size change | 3 (5) | 1 (2) |
| Pneumothorax | 0 | 2 (3) |
| Abdominal perforation | 1 (2) | 2 (3) |
| Unplanned extubation | 0 | 1 (2) |
| First intubation episode, n (%) | 42 (65) | 43 (65) |
| Nasogastric/orogastric gavage or feeding tube in-situ during PPV, n (%) | 5 (8) | 8 (12) |
| Mask hold, n (%): | | |
| Stem hold[a] | 9 (14) | 7 (11) |
| Two-point top hold[a] | 52 (80) | 55 (83) |
| OK rim hold[a] | 2 (3) | 2 (3) |
| Other | 2 (3) | 2 (3) |

SD, standard deviation; IQR, interquartile range; PPV, positive pressure ventilation.
[a]As described by Wood et al.[18]

variable, exposing the infant to risks of both volu-trauma and underventilation. An airway device that delivered nominal and consistent leak, would allow the use of minimal pressures to deliver a safe tidal volume.

### *Comparison with relevant findings from other published studies*

Despite the importance of newborn PPV only five randomised controlled trials published to date assessed various delivery interfaces.[10,28,33–35] A recent trial compared smaller facemasks with larger diameter facemasks for the administration of PPV in the delivery room and did not find a significant difference in facemask leak. Similar to our study, the masks compared were manufactured by Laerdal, and Fisher and Paykel. A facemask leak of 30–35% in 56 infants with a higher mean gestational age (28 weeks') at birth was reported.[10] Our results are consistent with this study.

Intubation of preterm infants in the neonatal intensive care unit is associated with a high rate of physiological instability,[36] which we also report. The cause of physiological instability during PPV is likely to be multifactorial. While previous studies examining the intubation of premature infants have focused on the duration of attempts,[37] the equipment used,[16] and operator experience,[38] our findings of high leak during PPV prior to and between intubation attempts, indicate that poor facemask technique may be partly responsible. We suggest that measures aimed at improving patient safety during infant intubation should include examination and improvement of the quality of PPV provided. Despite low oxygen saturations, an adequate heart rate (>100 beats per minute) was maintained. This is likely due to the provision of atropine prior to intubation attempts to the majority of our infants (94%).

Despite high facemask leak, we found that corrective steps such as mask repositioning occurred infrequently. Although not directly assessed, this implies that poor quality facemask ventilation was unrecognised. Poor recognition of facemask leak has previously been reported[39] and the addition of respiratory function monitors[9] or exhaled carbon dioxide detectors[40] to guide facemask ventilation have been proposed and warrant further investigation.

**Table 2 – Operator experience.**

| Outcome | Standard mask n=65 | Smaller mask n=66 |
|---|---|---|
| Role, n (%) | | |
| Fellow | 11 (17) | 10 (15) |
| Resident | 49 (75) | 56 (85) |
| Consultant | 5 (8) | 0 |
| Duration of neonatal practice, n (%) | | |
| <3 months | 13 (20) | 10 (15) |
| 3–6 months | 20 (31) | 20 (30) |
| 7–12 months | 11 (17) | 16 (24) |
| 1–2 years | 5 (8) | 6 (9) |
| 3–5 years | 9 (14) | 3 (5) |
| >5 years | 5 (8) | 0 |

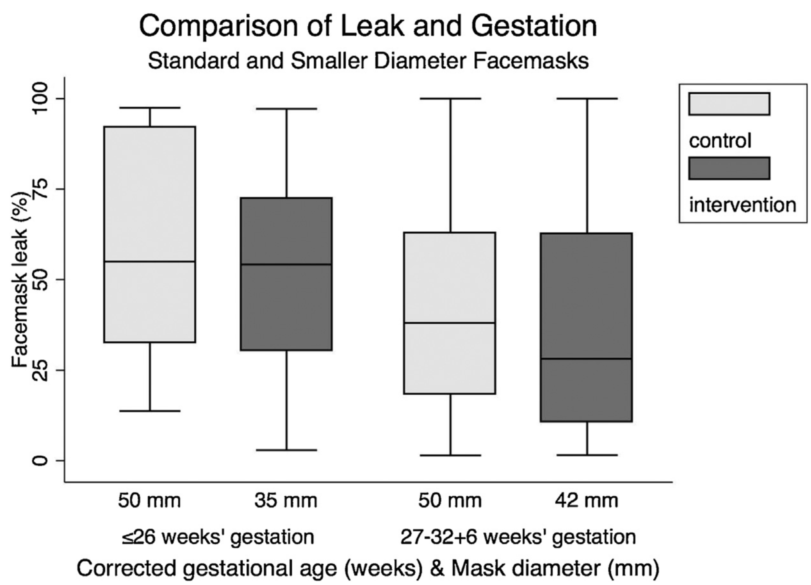


**Fig. 2 – Comparison of leak in different diameter facemasks.**
**Legend: The line inside each box represents the median, the top and bottom of the box represent the interquartile range, the whiskers represent the adjacent values (most extreme values within 1.5 IQR of the nearest quartile).**

**Table 3 – Primary and secondary outcomes.**

| Outcome | Standard mask n=65 | Smaller mask n=66 | Difference in means/ medians | *P*-value |
|---|---|---|---|---|
| Mask Leak (%) median (IQR) | 39 (22–66) | 42 (13–69) | 4 (−12 to 20)[a] | 0.43 |
| Duration of mask ventilation (s), mean (SD) | 87 (66) | 74 (54) | 14 (−7 to 35)[a] | 0.18 |
| Number of inflations, median (IQR) | 69 (33–157) | 62 (34–99) | −6 (−36 to 25)[a] | 0.20 |
| Expired tidal volume (ml/kg), mean (SD) | 12.6 (6.6–16.6) | 9.7 (4.9–14.4) | −2.9 (−6.3 to 0.6)[a] | 0.08 |
| Peak inspiratory pressure ($cmH_20$), mean (SD) | 24 (4) | 24 (3) | 0 (−1 to 1)[a] | 0.96 |
| Positive end expiratory pressure ($cmH_20$), mean (SD) | 4.6 (0.2) | 4.4 (0.2) | 0.3 (−0 to 1)[a] | 0.38 |
| Percentage of obstructed inflations, median (IQR) | 0 (0–0) | 0 (0–2) | 0 | 0.25 |
| Number of mask repositioning events, median (IQR) | 0 (0–1) | 0 (0–0) | 0 | 0.51 |
| Highest inspired oxygen (%), median (IQR) | 0.9 (0.6–1.0) | 0.8 (0.6–1.0) | −0.1 (−0.3 to 0.7)[a] | 0.39 |
| Lowest oxygen saturation during mask ventilation (%), median (IQR) | 71 (40–93) | 70 (34–93) | −2 (−22 to 18)[a] | 0.75 |
| Lowest heart rate during mask ventilation (beats per minute), mean (SD) | 149 (27) | 151 (26) | −2 (−11 to 8)[a] | 0.88 |

SD, standard deviation; IQR, interquartile range.
[a] Difference (95% confidence interval).

**Table 4 – Subgroup analysis.**

| Outcome | Standard mask | Smaller mask | *P*-value |
|---|---|---|---|
| ≤26 weeks' gestation | Laerdal (n=12) | F& P 35 mm (n=12) | |
| Mask leak (%), mean (SD) | 60 (32) | 51 (28) | 0.44 |
| 27–32 weeks' gestation | Laerdal (n=53) | F&P 42 mm (n=54) | |
| Mask leak (%), median (IQR) | 38 (18–62) | 34 (11–65) | 0.59 |

SD, standard deviation; IQR, interquartile range.

### *Generalisability*

While the recruitment of infants that received PPV both in the neonatal intensive care unit and in the delivery room improves generalizability of the results, the majority of the infants (94%) were recruited in the neonatal intensive care unit. It is therefore difficult to extrapolate these results to the delivery room.

### *Limitations*

Limitations of this study include the large percentage of eligible infants (53%) that were not recruited, potentially introducing a source of bias. This was due to the urgency with which clinical staff felt intubations should occur, with insufficient time to allow researchers to set up the monitoring equipment, and limited researcher availability. These issues were identified during recruitment, and measures such as expanding eligibility criteria, staff retraining, increased researcher availability, and audiovisual cues and reminders improved the recruitment rate. It was not possible to blind the intervention to the clinicians, however respiratory data was blinded to the operator during PPV.

### *Clinical/research implications*

This study indicates that current facemasks commonly used to perform infant ventilation are compromised by high leak and oxygen desaturation. While it has previously been recognized that administering PPV to premature infants with a round 50 mm internal diameter soft silicone mask is problematic, we found that smaller (35 and 42 mm) facemasks did not reduce facemask leak or improve physiological stability during PPV. These findings indicate that there is an urgent need for improved facemask design or other interfaces to provide PPV to very preterm infants, or to design a feedback mechanism to the clinician providing PPV in order to recognize mask leak and potentially enhance mask ventilation performance. In tandem, neonatal resuscitation guidelines specifying preterm mask size and placement, and teaching methods to measure, correct and optimize operators' clinical skills are needed. Preterm infants at the earliest gestations, are most in need of new innovations.

## Conclusion

Using a smaller mask to administer PPV to preterm infants did not reduce facemask leak. Facemask leak and physiological instability are high in preterm infants receiving PPV, in particular in those $\leq$26 weeks' gestation. Factors other than size may need to be improved when designing facemasks for this population and future research should investigate the influence of mask malleability, shape rim and hold on the quality of facemask ventilation.

## Conflicts of interest

The authors have no conflicts of interest relevant to this article to disclose.

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## Disclaimer

The views expressed in the article are the authors' own and are not an official position of the institution or funder. The authors have no financial relationships relevant to this article to disclose.

## Trial protocol

Available at anzctr.org.au, Australian New Zealand Clinical Trial Registry, ACTRN12614000709640, www.anzctr.org.au.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.resuscitation.2018.12.005.

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