Respiratory monitors to teach newborn facemask ventilation: a randomised trial

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Received 27 August 2018
Revised 15 December 2018
Accepted 17 December 2018

ABSTRACT

Objective The International Liaison Committee on Resuscitation has found that there is a need for high-quality randomised trials of training interventions that improve the effectiveness of resuscitation skills. The objective of this study was to determine whether using a respiratory function monitor (RFM) during mask ventilation training with a manikin reduces facemask leak.

Design Stratified, parallel-group, randomised controlled trial. Outcome assessors were blinded to group allocation.

Setting Thirteen hospitals in Australia, including non-tertiary sites.

Participants Consecutive sample of healthcare professionals attending a structured newborn resuscitation training course.

Interventions An RFM providing real-time, objective, leak, flow and volume information was attached to the facemask during 1.5 hours of newborn ventilation and simulation training using a manikin. Participants were randomised to have the RFM display visible (intervention) or masked (control), using a computer-generated randomisation sequence.

Main outcome measures The primary outcome was facemask leak measured after neonatal facemask ventilation training. Tidal volume was an important secondary outcome measure.

Results Participants were recruited from May 2016 to November 2017. Of 402 eligible participants, two refused consent. Four hundred were randomised, 200 to each group, of whom 194 in each group underwent analysis. The median (IQR) facemask leak was 23% (8%–41%) in the RFM visible group compared with 35% (14%–67%) in the masked group, p<0.0001, difference (95% CI) in medians 12 (4 to 22).

Conclusions The display of information from an RFM improved the effectiveness of newborn facemask ventilation training.

Trial registration number ACTRN12616000542493, pre-results.

What is already known on this topic?

- Effective mask ventilation is the cornerstone of successful newborn resuscitation.
- It is a difficult skill to perform, substantial facemask leak and airway obstruction are common and can impede delivered Vt, lung aeration and oxygenation.
- Written instruction combined with demonstration reduces facemask leak.

What this study adds?

- A respiratory function monitor allows the teacher and learner to objectively measure the quality of mask ventilation during teaching sessions.
- Teaching mask ventilation on a manikin with a visible respiratory function monitor screen leads to significantly better mask ventilation skills.
- This trial included a large proportion of resuscitators in non-tertiary settings, who are an understudied population.

INTRODUCTION

The International Liaison Committee on Resuscitation has recently identified the need for high-quality randomised trials of training interventions that improve the effectiveness of clinical resuscitation skills.[1] Ineffective newborn resuscitation is a global health issue, with 700 000 deaths per year attributable to intrapartum events.[2] Newborn resuscitation offers an opportunity to save many lives.[3] To be effective it must be rapidly administered by healthcare staff with sufficient training.[4] Facemask ventilation skills have been found to be poor even after training, indicating that current teaching methods are inadequate.[5] Newborn facemask ventilation is a difficult skill to master and must be performed accurately, with risks of harm from both underventilation and overventilation.[3] Facemask ventilation is frequently compromised in newborns by a large and variable facemask leak and by airway obstruction.[6 7] Facemask leak of 30%–54% has been reported,[6 8 9] and operators are frequently unaware of this problem.[6 8] When learning and performing facemask ventilation, operators lack objective methods to assess and improve their technique.[10] Neither assessment of chest rise nor measurement of peak inspiratory pressure correlates well with delivered tidal volume (Vt).[11]

Respiratory function monitors (RFM) can be used to evaluate the effectiveness of facemask ventilation.[12] They are capable of measuring and displaying Vt, flow and leak in real time, however their role in training has not been explored.[13] Feedback devices have a sound basis in learning theory as teaching tools, improving motor skills through active experimentation and deliberate practice, however they do not uniformly improve

To cite: O'Currain E, Thio M, Dawson JA, *et al*. *Arch Dis Child Fetal Neonatal Ed* Epub ahead of print: [*please include* Day Month Year]. doi:10.1136/archdischild-2018-316118

performance.[14 15] An RFM may assist in learning technique by providing objective, real-time, visual feedback of effectiveness to the clinician.[16] The International Liaison Committee on Resuscitation has identified that the use of 'flow and volume monitoring' (eg, RFMs) to improve and teach newborn resuscitation skills is a specific knowledge gap that should be addressed.[1] The aim of this study was to determine whether the addition of an RFM during newborn resuscitation training reduced facemask leak.

METHODS

Study design

This was a multicentre, outcome assessor-blinded, parallel-group, randomised controlled trial conducted in 13 hospitals in Australia. Participants were randomised with a 1:1 allocation ratio and crossover between intervention groups was not permitted. The study was integrated within the Victorian Neonatal Resuscitation Training Programs (NeoResus), delivered by the Royal Children's Hospital's educational staff at multiple locations across the Australian state of Victoria,[16] and designed to train clinicians in tertiary and non-tertiary centres.

Participants

Healthcare professionals (doctors from any specialty, midwives, nurses, paramedics, medical students, nursing students or midwifery students) attending the NeoResus training programme were eligible to participate in the study. Participants from any level of neonatal acuity (community, primary, secondary or tertiary care) were eligible. Prior written informed consent was obtained from all participants.

Randomisation

Eligible participants were randomly assigned to a group in which the RFM display was either visible (intervention) or masked (control) in separate rooms. A computer-generated randomisation sequence, independently created at the Murdoch Children's Research Institute, was used. To comply with the programme requirement to train in multidisciplinary groups, a fixed block size of 2 was chosen to ensure that each multidisciplinary group was balanced during each course and that a minimum of one doctor, nurse and midwife were present in each group. Allocation concealment was maintained by randomising in order of consent in even numbers. Randomisation lists were stratified according to professional role into three groups: (1) doctor, (2) midwife, (3) nurse/other healthcare professional/student. Participants were allocated using sequentially numbered, sealed, opaque envelopes containing the group assignment. Participants and instructors were aware of their allocated group during training, outcome assessors and the data analyst were blinded to the allocation. Participants and instructors were blinded to the respiratory data during baseline and outcome data collection by masking the monitor and computer displays.

Interventions

The intervention and control groups were taught in separate rooms by separate instructors. Facemask ventilation training consisted of demonstration, deliberate practice and two simulation sessions. Each learner performed mask participated in a minimum of one simulation. Standardised simulations consisted of (1) an apnoeic newborn and (2) an apnoeic and bradycardic newborn and included preparation, role allocation, initial stabilisation, airway management, facemask ventilation and chest compressions. In both simulations each team member participated in their usual role, with midwives or nurses providing initial resuscitation and doctors providing ongoing management. All training was carried out by a NeoResus instructor, independent of the research team and rotating between courses. All instructors were given the trial protocol and were trained in the interpretation of the RFM with visual aids depicting low leak, high leak and obstructed waveforms. Facemask ventilation instruction and corrective instructions, standardised with a checklist, consisted of facemask holds, positioning and airway techniques as described by Wood *et al*.[17] The intervention group were trained on the interpretation of the RFM waveforms with visual aids, as above. Instructors were allowed to verbally state the leak and Vt that the learner was achieving but did not assist in interpretation of RFM signals. Participants in the intervention group continued deliberate practice with visual RFM feedback until minimal leak was achieved. In response to RFM feedback, participants adjusted the airway position, mask placement or mask hold until an improvement was seen. Participants in the control group followed the same practice with the flow sensor and masked RFM display in situ until adequate chest rise was observed.

Ventilation was performed using a Neopuff Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand), a pressure limited T-piece device. Initial settings were a gas flow of 8 L/min, peak inflating pressure of 30 cmH_2O and positive end expiratory pressure of 5 cmH_2O. A size 0/1 Laerdal round facemask was used (Laerdal Silicone facemask, Laerdal, Stavanger, Norway). A Laerdal Resusci Baby manikin was modified by inserting a 50 mL test lung (Dräger, Lubeck, Germany) to create a leak-free system, as previously described.[13] A Florian respiratory monitor (Acutronic Medical Systems, Switzerland) measured airway flow and gas pressure using a dual hot wire anemometer flow sensor, placed between the facemask and T-piece. The monitor integrates the flow signal to calculate the Vt. Airway pressure was measured via a pressure line connected proximal to the test lung.[13] Respiratory data were captured and recorded using Spectra software (Grove Medical, London, UK). Respiratory waves were analysed inflation by inflation by a single researcher (EOC) using Spectra and LabChart software (ADInstruments, Dunedin, New Zealand). Facemask leak was defined as the difference between inflating and deflating ('expiratory') Vt, expressed as a percentage of the inflating volume.[13] For each individual participant a mean leak of all the inflations performed during the assessment period was calculated. Respiratory data during mask ventilation were measured twice, before training to obtain baseline data and immediately after the training period to measure outcome data.

Outcome measures

The primary outcome measure was mean facemask leak during participant mask ventilation, performed shortly after the ventilation training session. For half-day 'first response' courses this was at the completion of their training, for the full-day 'advanced' programme, this marked the halfway point. The post-training facemask leak was compared between the control and intervention groups. During all assessments, each participant performed facemask ventilation for 30 s, blinded to the RFM and without instruction. Secondary outcomes were expired Vt and stability of Vt (SD). Peak inflating pressure data were also collected. Facemask leak post-training was chosen as the primary outcome, as it is an objective and measurable training outcome that has frequently been reported in newborn resuscitation studies.[8 9 11] Facemask leak is also directly attributable to the device used, as

opposed to Vt, which is dependent on multiple factors such as lung compliance, respiratory disease and positive airway pressure administered. While Vt is an important secondary outcome in this study, it was not possible to select a meaningful range to target in a manikin model.

Statistical analysis

Facemask leak of 30%–54% has been reported in neonatal facemask ventilation studies in tertiary settings.[6 8 9] As our participants were recruited from both tertiary and non-tertiary settings, we assumed a mean leak of 50% in the control group and an SD of 30%. To detect a clinically significant 10% absolute difference in post-training leak (50% vs 40%) between the intervention and control arms, a sample size of 382 (191 in each arm, with 90% power, two-tailed alpha error of 0.05) was required.

Continuous data are presented as mean (SD) for normally distributed variables and median (IQR) when the distribution is skewed. Continuous data from each participant were summarised as mean or median. Outcome variables were analysed by using the Student's t-test for parametric comparison and Mann-Whitney U test for non-parametric comparison of continuous variables. Differences of means and 95% CIs were estimated using the Student's t-test and differences of medians and 95% CIs were estimated using quantile regression analysis. Categorical data are expressed as number and percentages and were analysed using the X^2 test. The Spearman correlation coefficient was used to estimate the relationship between leak and the operators' years of experience. Data were analysed using Stata software (Intercooled V.14, StataCorp, College Station, Texas, USA).

RESULTS

Participants were recruited from 12May 2016 to 10November 2017. Recruitment was stopped when the predefined sample size was achieved. Participants were recruited at 13 NeoResus courses. Four hundred and two participants were assessed for eligibility at 38 courses and were approached for consent to participate. Two refused consent. Four hundred were randomised and 388 were analysed, 194 in each group (figure 1). An intention-to-treat analysis was performed. Twelve postrandomisation exclusions occurred as there was a failure to record the primary outcome data at one course due to human error. Six of these exclusions were in each group. Participants consisted of 102 (31%) doctors, 182 (47%) midwives and 104 (27%) nurses/other professional/student. Demographic characteristics in both groups were similar (table 1). Participants worked in a wide variety of settings (primary, secondary and tertiary neonatal care) and locations throughout Australia (table 1).

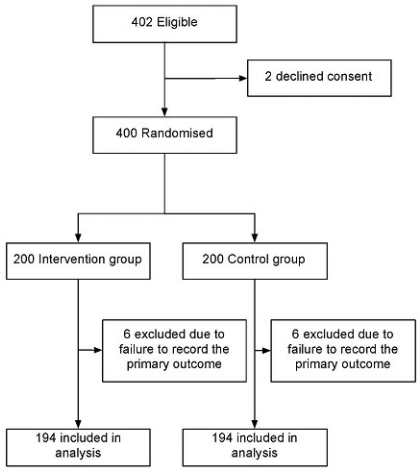

Figure 1 Participant flow diagram. Recruitment and allocation.

Table 1 Comparison of demographic characteristics between the study arms

Characteristic	Detail	Intervention (n=200)	Control (n=200)
n (%) with data		194 (97)	194 (97)
Sex, n (%)	Male	18 (9)	22 (11)
Professional role, n (%)	Doctor	51 (26)	51 (26)
	Midwife	91 (73)	91 (73)
	Nurse/other*	52 (11)	52 (11)
Workplace, n (%)	Community/home births	7 (4)	4 (2)
	Primary care inpatient	86 (44)	83 (4)
	Secondary care inpatient	69 (36)	72 (4)
	Tertiary care inpatient	21 (11)	26 (13)
	Multiple workplaces	11 (6)	9 (5)
Experience in newborn care (years), median (IQR)		8 (3–17)	8 (2–18)
Newborn PPV in previous year (n), median (IQR)		1 (0–3)	1 (0–3)

*Other: allied health professionals, health professional students.
PPV, positive pressure ventilation.

The pretraining median (IQR) leak in the visible RFM group was 63% (22%–90%) compared with 51% (22%–80%) in the masked RFM group. The median (IQR) leak after training in the visible RFM group was 23% (8%–41%) compared with 35% (14%–67%) in the masked RFM group, p<0.0001, difference (95% CI) in medians 12 (4 to 22) (figure 2). The intervention group had a 22% higher median (IQR) expiratory Vt, 18.2 mL (14.8–20.6 mL) vs 14.9 mL (10.7–18.6 mL) in the control group, p<0.0001. There was no evidence of an important difference in peak inflating pressure (p=0.13) (table 2). Leak was not associated with the operator's years of experience (r=0.05, p=0.34).

DISCUSSION

In this multicentre, randomised trial the addition of an RFM to teach newborn facemask ventilation reduced facemask leak and increased delivered volume. Less variability in leak and tidal

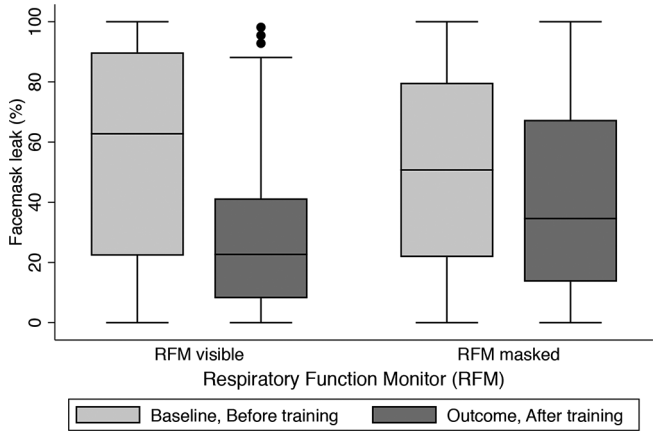

Figure 2 Comparison of leak (%) with respiratory function monitor (RFM) visibility, before and after training. The line inside each box represents the median, the top and bottom of the box represent the IQR and the whiskers represent the adjacent values (most extreme values within 1.5 IQR of the nearest quartile). Circles plotted beyond the whiskers represent outliers.

Table 2 Comparison of respiratory measurements after training in 388 participants

Variable	RFM visible n=194	RFM masked n=194	Difference (95% CI) in post-training medians/means	P value
Leak (%)				
Pretraining, median (IQR)	63 (22–90)	51 (22–80)		
Post-training, median (IQR)	23 (8–41)	35 (14–67)	12 (4 to 22)*	<0.0001
Expiratory Vt (mL)				
Pretraining, mean (SD)	14.2 (7.5)	14.1 (6.4)		
Post-training, mean (SD)	17.7 (4.9)	14.2 (6.4)	3.5 (2.4 to 4.7)†	<0.0001
Peak inflating pressure (cmH_2O)				
Pretraining, mean (SD)	28 (6)	29 (5)		
Post-training, mean (SD)	30 (3)	30 (4)	−0.6 (−1.3 to 0.2)†	0.13

*Difference in medians (95% CI).
†Difference in means (95% CI).
RFM, respiratory function monitor; Vt, tidal volume.

volume was also observed after training with the RFM. The delivery of minimal leak with minimum variability is desirable in a clinical setting, as this allows delivery of a safe, consistent tidal volume with the use of minimal inspiratory pressures, and protects from volutrauma or underventilation.

We performed a systematic review of newborn resuscitation training interventions and searched five databases (Medline, Embase, CINAHL, Academic Search Complete and the Cochrane Library) using the following terms: ([newborn or neonatal OR infant] AND resuscitation AND [train* OR teach* or NRP OR NLS OR simulation]). We found 37 randomised studies and two meta-analyses. Evidence from a meta-analysis of three cluster randomised trials in low/middle-income countries found that standardised formal newborn resuscitation training reduced early newborn mortality.[18] With the exception of videolaryngoscopy to teach newborn intubation,[19] there is little high-quality evidence for training interventions that improve specific clinical resuscitation skills. In a randomised cross-over study, Wood *et al* reported that facemask leak was high, different holds were most suitable for different masks and that written instruction alone when combined with demonstration leak was reduced by 24%.[17] These studies highlight the complexities of teaching this basic skill and the need for objective measures of performance to guide learning.

Our study had several limitations. Simulation or manikin-based studies cannot be directly translated into clinical practice. Administration of mask ventilation in the clinical setting is further complicated by infant movement, variability in facial dimensions and spontaneous breaths.[8] Our model could not measure airway or glottic obstruction which may impede ventilation in clinical practice, particularly if excessive mask pressure is applied.[20] While we reduced leak in this study, improving facemask ventilation in practice may be more complex. However, despite the limitations of simulation there is emerging evidence that simulation assessment of emergency clinical skills has a high validity, that is, learner's performance in simulation is reflective of their performance in clinical practice.[21] While measurement of leak and tidal volume help gauge the effectiveness of ventilation, an understanding of newborn transition and physiology are equally important.[4 22] The geographical spread of our participants (up to 3668 km from the trial coordination site) meant we could not undertake clinical follow-up or repeat testing. Randomised controlled trials of newborn resuscitation training infrequently report clinical outcomes and a cluster randomised approach may be a more suitable trial design to assess these outcomes.[1] It has been established that newborn resuscitation skills can deteriorate over time, therefore we cannot conclude that the improvement shown in this trial will be retained on a long-term basis.[23 24] However, Schilleman *et al* demonstrated that a reduction in newborn mask leak immediately after training was maintained 3 weeks later.[25] Despite the observed improvement, some leak persisted after training, indicating that our training model could be improved. Deliberate practice of skills competes with knowledge, behavioural and team training during resuscitation training, and some participants may have benefited from increased exposure to the RFM. RFMs also require some training in their interpretation, which may limit the widespread adoption of our training model without further refinement of the monitor's portability and data display. We hypothesise that coded colours may increase the ease of interpretation.

The strengths of our study are that we have identified and developed an effective, feasible and important education intervention that can objectively improve resuscitators skills. Our trial findings are consistent with observational studies that showed a reduction in facemask leak with the use of an RFM during positive pressure ventilation training.[26] In an observational study, Binder *et al* investigated positive pressure ventilation combined with chest compressions and an RFM and reported a 68% reduction in facemask leak with RFM use.[27] These observational studies only included personnel from tertiary neonatal units. The diversity of experience and roles is a strength of the current study, improving the generalisability of our results. Six of our study sites deliver <500 newborns per year where there is a shortage of experiential learning opportunities to gain and maintain resuscitation skills.[28] Previous research including this population of resuscitators is limited.

Considering underlying mechanisms for our findings, we suggest that the visual feedback provided by the RFM allows the learner to improve their technique through deliberate practice and experimentation. Deliberate practice, as outlined by Ericsson,[15] includes well-defined learning objectives, precise measurement of performance, repeated focused repetition of the task and objective feedback on performance. Our educational model provided clearly defined learning goals and objectives, that is, leak <10%, and enhanced the focused repetition of a traditional simulation training session with precise measurements of performance. The feedback provided by the RFM allowed the learner to correct their mistakes by adjusting their hold, the facemask position or the airway position and for effective deliberate practice to occur.

CONCLUSION

This randomised controlled trial indicated that the measurement and feedback of objective respiratory data is associated with improved newborn facemask ventilation skills. Further research on the clinical translation and retention of this improvement is warranted.

Acknowledgements We thank all the participants for their invaluable contribution to this study and the staff at the Royal Women's Hospital newborn research department for their support. We also thank the PIPER education department staff for their support of the project.

Contributors EOC made significant contributions to the study design, wrote the first draft of the protocol, collected data, carried out the initial analysis and data interpretation, and wrote the first draft of the manuscript. JAD conceptualised and designed the study, collected data, and reviewed and revised the manuscript. SMD made significant contributions to the design of the study, statistical plan, data analysis and interpretation, and reviewed and revised the manuscript. MT and PGD conceptualised and designed the study, supervised the project and critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Funding This study was supported by the Australian Government National Health and Medical Research Council (App ID 1059111 to PGD, App ID 1111134 to MT, App ID 1113902 to PGD, JAD and MT, App ID 1060733 to EOC via a PhD scholarship and project grant from the Centre of Research Excellence in Newborn Medicine, Murdoch Children's Research Institute).

Competing interests None declared.

Patient consent Not required.

Ethics approval The study was approved by the Royal Children's Hospital's Human Research and Ethics Department (HREC No 36031).

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Will individual participant data be available (including data dictionaries)? Yes. What data in particular will be shared? All of the individual participant data collected during the trial, after deidentification. What other documents will be available? Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code. When will data be available (start and end dates)? Beginning 3 months and ending 5 years following article publication. With whom? Researchers who provide a methodologically sound proposal. For what types of analyses? To achieve aims in the approved proposal. By what mechanism will data be made available? Proposals should be directed to eoin.ocurrain@thewomens.org.au; to gain access, data requestors will need to sign a data access agreement.

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