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Randomised study of a new inline respiratory function monitor (Juno) to improve mask seal and delivered ventilation with neonatal manikins

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ABSTRACT

Background Respiratory function monitors (RFMs) have been used extensively in manikin and infant studies yet have not become the standard of training. We report the outcomes of a new portable, lightweight RFM, the Juno, designed to show mask leak and deflation tidal volume to assist in positive pressure ventilation (PPV) competency training using manikins.

Methods Two leak-free manikins (preterm and term) were used. Participants provided PPV to manikins using two randomised devices, self-inflating bag (SIB) and T-piece resuscitator (TPR), with Juno display initially blinded then unblinded in four 90 s paired sequences, aiming for adequate chest wall rise and target minimal mask leak with appropriate target delivered volume when using the monitor.

Results 49 experienced neonatal staff delivered 15 569 inflations to the term manikin and 14 580 inflations to the preterm. Comparing blinded to unblinded RFM display, there were significant reductions in all groups in the number of inflations out of target range volumes (preterm: SIB 22.6–6.6%, TPR 7.1–4.2% and term: SIB 54.8–37.8%, TPR 67.2–63.8%). The percentage of mask leak inflations >60% was reduced in preterm: SIB 20.7–7.2%, TPR 23.4–7.4% and in term: SIB 8.7–3.6%, TPR 23.5–6.2%).

Conclusions Using the Juno monitor during simulated resuscitation significantly improved mask leak and delivered ventilation among otherwise experienced staff using preterm and term manikins. The Juno is a novel RFM that may assist in teaching and self-assessment of resuscitation PPV technique.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Mask leak is common, can be large in magnitude and produce ineffective ventilation.
⇒ Excessive tidal volumes may injure vulnerable preterm lungs and brain.
⇒ The optimum use of respiratory function monitors (RFMs) used in manikin training is not determined.

WHAT THIS STUDY ADDS

⇒ Mask leaks in excess of 60% significantly reduce delivered tidal volumes.
⇒ Optimising mask seal reduces high leak inflations in manikin models.
⇒ Optimising mask seal alone with T-piece resuscitator improves targeted volume delivery in manikin models.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Inline RFMs with simple graphical user interface can improve the delivery of resuscitation training at all levels of skill.
⇒ Further research to guide policy how often to train to retain skills is needed.
⇒ Further research will determine the effectiveness of this RFM as a tool for self-directed learning in rural or remote settings.

INTRODUCTION

Applying effective ventilation is one of the critical techniques used during newborn resuscitation. An essential characteristic is achieving adequate mask seal to deliver appropriate lung inflation during positive pressure ventilation (PPV).[1 2] This skill is required by a wide range of health practitioners and depends on repetitive training. As well as experienced neonatologists, first responders may include midwives, nurses and doctors not based in neonatal intensive care unit (NICU). The retention of resuscitation skills relies on practice and assessment using manikins, typically with no feedback on delivered ventilation, mask leak or functionality of resuscitation device. In many circumstances, manikins used to assess training skills may be limited by the range of size, structural characteristics (how much force is required to achieve an adequate seal) and functional system compliance. Damaged manikins can produce unrecognised and unintended internal leaks. These factors lead practitioners to apply more inflation pressure or mask force to achieve a given chest wall movement. Our research has shown that many brands of resuscitation devices in leak-free settings can fail to deliver adequate ventilation despite compliance with current international standards.[3]

Respiratory function monitors (RFMs) have been used in many manikins and human infant studies to quantitate mask seal as a prerequisite to appropriate delivered tidal volumes.[4 5] Most studies have used either commercial (Philips NM3, Acutronic Florian) or research RFMs that inform current guidelines on RFM use during newborn resuscitation.[6–10] They are expensive, heavy and complex monitors that require expert knowledge to use and are no longer commercially available. There is a need for a new class of monitor for resuscitation that enables the practitioner to visualise real-time data in an optimal display of

Figure 1 The ResusRight Juno monitor pre-commercial prototype studied.

ventilation performance and prompt immediate adjustment if there is an excessive face mask leak or inappropriate delivered volumes.

This paper describes the assessment of a novel resuscitation monitor, the 'Juno' monitor, built by ResusRight[11] and used in this manikin study. The monitor is a miniaturised battery-driven RFM small enough to fit between the patient interface (face mask, laryngeal mask or endotracheal tube) and resuscitation device. The LED screen has been designed to be in the line of sight with the manikin or baby without obscuring rise and fall of the chest. The graphical user interface (GUI) is an LED screen that displays easily interpreted icons (three baby sizes), a 'traffic light' system for mask leak range and an absolute deflation tidal volume (Vte) for the experienced user. Thus, critical information relating to deflation/expired tidal volume in millilitres according to the size of the infant being resuscitated and mask leak can be interpreted at all levels of experience (figure 1, online supplemental figure 1).

We aimed to compare the mask leak and deflation tidal volumes using the Juno resuscitation monitor, with the display screen blinded and unblinded using two different-sized manikins (Laerdal Premature Anne and the Laerdal ALS infant manikins) and two different inflation devices: Ambu self-inflating bag (SIB) and Fisher & Paykel Neopuff T-piece resuscitator (TPR). Our null hypothesis was that there would be no difference in the targeted delivered volumes, and mask leak applied to the manikins with or without the Juno monitor display unblinded or blinded.

MATERIALS AND METHODS

Setting

Staff of a newborn intensive care nursery at a major metropolitan teaching hospital (Westmead Sydney, Australia) were invited to participate. Forty-nine experienced NICU staff (nurses, nurse practitioners, doctors: junior and senior) consented to participate. All had previously received extensive training in neonatal resuscitation, demonstrating proficiency annually in the locally run NICU resuscitation course. This course uses the American Academy of Paediatrics neonatal resuscitation programme.[12] The mask hold taught for a single person is the two-point top.[1] Importantly, all participants had received repeated training and exposure to the Juno resuscitation monitor, were familiar with volume targeting and mask leak indication during PPV and were assessed to be confident in using the monitor before the study.

Manikins

We used the Laerdal ALS trainer infant (#08003040) and the Premature Anne (#290-00050) manikins. Both were tested for leaks and found to be leak-free. Both manikins have a hinged mandible allowing for realistic jaw thrust. The ALS infant manikin is a closed system with lung and stomach bags; the oesophageal tube was blocked for this study. Static compliance was measured at 2.4 mL/cmH_2O. The Premature Anne approximates a 25-week preterm manikin with measured static compliance of 0.6 mL/cmH_2O.

Ventilation devices

A new disposable Ambu Spur II Infant Self Inflating Bag (volume 220 mL) with reservoir bag (#335 102 000), Ambu disposable PEEP valve 20 (#199 102 001) and Ambu manometer (#322 003 000) attached (Ambu A/S Ballerup, Denmark) were used with each participant. No auxiliary gas inflow was used. The TPR used was a Neopuff infant (#RD900, Fisher & Paykel

Healthcare, New Zealand) with gas inflow set to 10 L/min. The mask used were Ambu triangular disposable face mask (#000 252 952) for term and Fisher & Paykel Neonatal resuscitation 35 mm mask preterm (#RD803).

The resuscitation monitor (Juno)

The Juno is a lightweight (85 g), inline, battery-driven (run-time 5 hours) RFM. The Juno monitor studied was a pre-commercial prototype (SW V.0.2.4) displaying: mask leak grouped by a traffic light LED panel (green reflecting leak from 0% to 29.9%, orange 30% to 59.9% and red ≥60% to 100%) with ranges based on leak significance reported in previous studies[2 4 13]; deflation tidal volume in millilitres as well as baby range icons (small 2.5–9.9 mL, medium 10–24.9 mL and large 25–50 mL) estimated based on resuscitation guidelines and inflation rate per minute.[14] Displayed data is updated for each inflation in real time. Small and large baby volume icons change red to indicate low (<2.5 mL) and excessive (≥50 mL) Vte, and a no-breath icon indicates after 5 s of no airflow detected (online supplemental figure 2). The monitor is situated in the line of sight of the chest wall, thus enabling the resuscitator to visualise the monitor and the chest wall at the same time.

The Juno monitor uses a thermal mass flow pneumotach to detect flow in the cuvette with a dead space (0.9 mL)[15] similar to clinically used neonatal pneumotach[16] and has inbuilt memory, storing inflation-by-inflation data. The Juno monitor does not measure pressure, only flow that integrates into volumes. It was extensively validated with traceable reference testing systems. Volume reference using calibrated precision syringes (Hans Rudolph series 5520)[17] ±0.05 mL and calibrated flow reference testing ±1.75% of reading or ±0.05 sL/min (IMT Analytics AG Flow Analyser PF-300).[18] Juno was found to be well within stated accuracy ±8% of volume readings. Data stored is time, inflation/deflation tidal volume (Vti, Vte) and inflation/deflation time (Ti, Te)). The Juno is approved for use in neonatal resuscitation training in Australia and Europe, but it is not currently approved for clinical use in humans.

Data collection

Two separate data collection sessions were carried out, one for each manikin size. Participants were randomised for starting resuscitation device (TPR or SIB); the Juno device was in situ for all combinations. The Juno display was initially blinded for each resuscitation device.

Participant instructions

With the Juno display blinded, the task was to provide 90 s of mask PPV to the manikin to achieve adequate chest wall rise and use a rate between 40 and 60 inflations per Neonatal Resuscitation Program guidelines.[12] For the preterm manikin, the target pressures were 20 cmH_2O peak inspiratory pressure (PIP) and PEEP 5 cmH_2O (SIB: PEEP preset and PIP targeted by manometer; TPR preset to 20/5). For the term manikin, target pressures were 25 cmH_2O PIP and PEEP 5 cmH_2O (SIB: PEEP preset and PIP targeted by manometer; TPR preset to 25/5).

With the Juno display unblinded, the task was to provide 90 s of PPV to the manikin to achieve adequate chest wall rise and use a rate between 40 and 60 inflations per minute. Participants were asked to use the mask leak visual indicators (figure 1) to optimise the mask seal by adjusting their mask hold technique if necessary (if the leak indicator was red or orange) and when using SIB target appropriate PIP to achieve targeted volumes, using either the actual Vte volume display (preterm 4–6 mL, term 25–30 mL) or the baby icon volume range (small baby 2.5–10 mL or large baby icon baby 25–50 mL). With TPR use, participants were asked to minimise mask leak only (they did not adjust TPR PIP to target Vte, PIP remained at the pre-set value). Participants had a 2 min rest between changes in display status or resuscitation device used. Data were downloaded via USB-C cable. Less experienced staff were encouraged to use the icons to determine volumes.

Data analysis

Analysis was conducted using Stata (V.17 MP). The measured test lung parameters were Vti, Vte, Ti and Te. Mask leak percentage was calculated using the formula ((Vti−Vte)/Vti) ×100. A priori the first two inflations (mask applied) and the last inflation (mask released) were removed. Inflations during mask seal adjustments typically resulted in Vti/Vte/Ti/Te outside meaningful ranges and were removed. These reflected mask seal adjustment periods (prior validation bench assessments). Mask leaks with negative values between −15% and 0% were examined and re-coded to 0 leak %. Negative leaks <−15% were discarded. A total of 1452 (8.49%) inflations for term manikin were removed and 2238 (13.8%) for preterm. Raw data were examined for distributional characteristics. We used univariate logistic regression to estimate ORs with 95% CIs and Pearson χ^2 tests to calculate p values to compare proportions between the study groups for the main dichotomous outcomes. For non-normally distributed data, we used non-parametric bootstrap median regression with 95% CIs to infer the observed significance of the effects (median deflation tidal volumes by leak group). Analysis of variance (ANOVA) for repeated measures was used to determine differences in predicted means between devices and screen unblinded or not adjusting for individuals. ANOVA was reported with p value adjusted F test using Box's conservative epsilon; p values of <0.05 were considered statistically significant.

RESULTS

There was a total of 14 580 inflations recorded with the preterm manikin (SIB 7356 (50.4%); NP 7224 (49.6%)) and 15 659 inflations with the term manikin (SIB 8160 (52%); NP 7499 (48%)). As mask leak increased by groups according to leak, the delivered inflation volume decreased significantly in both manikin models (figure 2 and table 1), p<0.001.

More inflations were delivered in the target range determined by both icon grouping and absolute Vte range when the Juno monitor was unblinded for both devices and manikins, p<0.005. There were consistently larger differences with the SIB group screen unblinded. Unblinded there were reductions in the number of inflations with mask leak >60% (term manikin: TPR 23.5% blinded vs 6.2% unblinded (OR −4.9) and with SIB 8.7% blinded vs 3.6% unblinded (OR −3.1)) (preterm manikin: TPR 23.5% blinded vs 7.4% unblinded (OR −1.5) and SIB 20.8% blinded vs 7.2% unblinded (OR −1.5)), p<0.001 (table 2). There was a significant reduction in predicted mean leak values in term manikin and TPR from predicted means of 29.9% blinded to 16.4% unblinded and with SIB 15.8% blinded to 10.5% unblinded (table 3). Similar significant reductions were seen for the preterm manikin with predicted mask leaks of TPR blinded mean 33.1% reduced to 18.4% and with SIB 38.0% reduced to 22.6%, p<0.001.

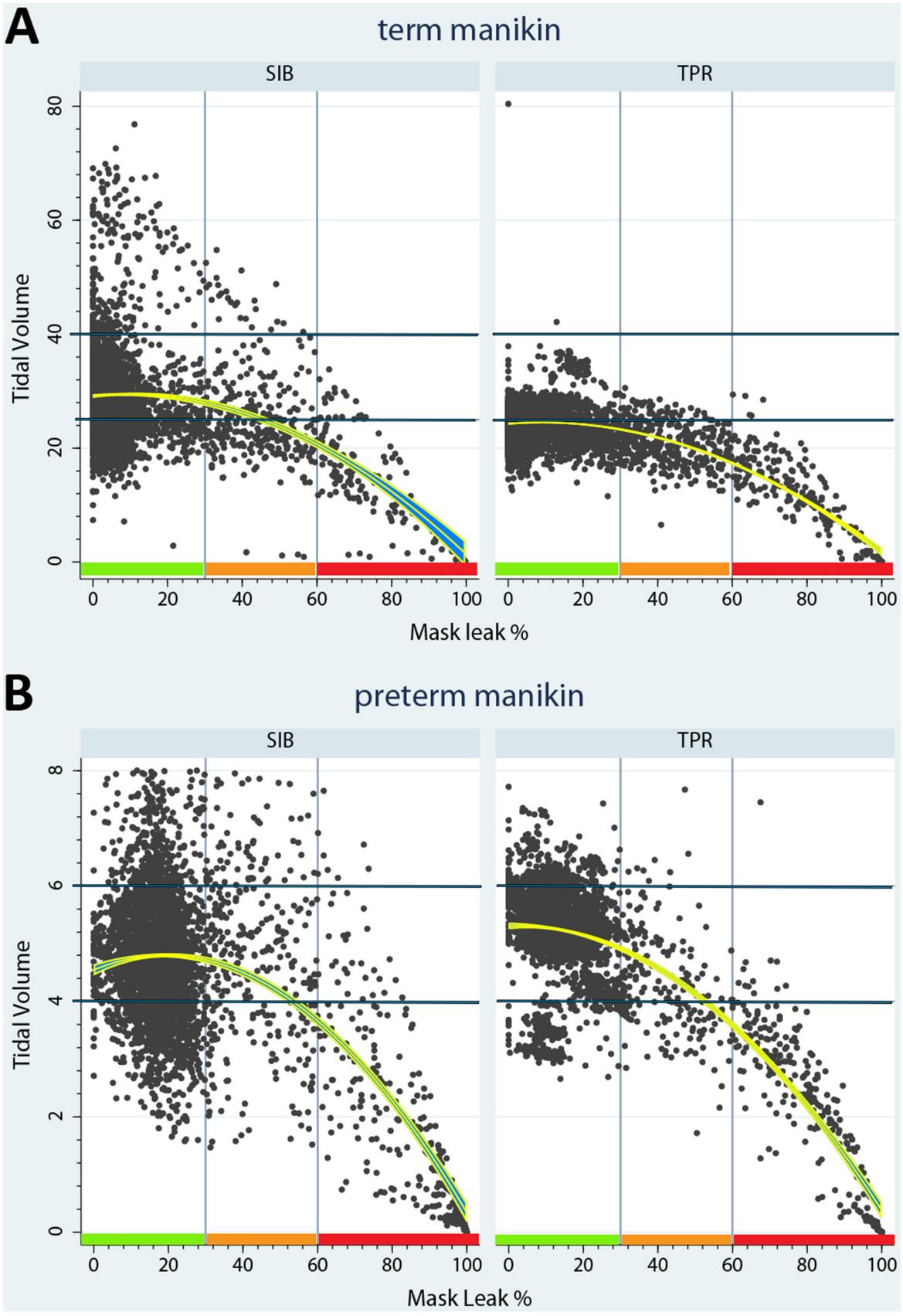

Figure 2 Term manikin (A) and preterm (B) scatter plots of inflations with Juno display unblinded. By ventilation device (self-inflating bag (SIB) and t-piece resuscitator (TPR)), target volume ranges 4–6 mL and 25–50 mL, and per cent leak category: green 0–29.9%, orange 30–59.9%, red 60–100% leak. Regression line is quadratic with 95% CI.

Table 1 Inflation count and percentage of delivered volumes in and out of target icon volume range and absolute volume range for all combinations of ventilation device, manikin type and Juno monitor display (blinded or unblinded)

	T-piece Resuscitator		Self-inflating bag		Total
	Blinded	Unblinded	Blinded	unblinded	
Bivariate analysis grouped by icon volume range (in range or not)					
Term					
In range 25–40 mL	1226 (32.8%)*	1359 (36.2%)*	1854 (45.2%)†	2547 (62.7%)†	
Out of range	2514 (67.2%)	2400 (63.8%)	2245 (54.8%)	1514 (37.8%)	
Inflations total	3740	3759	4099	4061	15 659
Preterm					
In range 2.5–10 mL	3271 (93%)*	3546 (95.8%)*	2548 (77.4%)†	3796 (93.4%)†	
Out of range	250 (7.1%)	157 (4.2%)	743 (22.6%)	269 (6.6%)	
Inflations total	3521	3703	3291	4065	14 580
Total inflations					30 239
Grouped analysis by absolute volume range (below, above and in range)					
Term					
Below range <25 mL	2514 (67.2%)†	2398 (63.8%)†	1525 (37.2%)†	1253 (30.9%)†	
In range 25–30 mL	1175 (31.4%)	1271 (33.8%)	841 (20.5%)	1421 (35.0%)	
Above range >30 mL	51 (1.4%)	90 (2.4%)	1733 (42.3%)	1387 (34.2%)	
Inflations total	3740	3759	4099	4061	15 659
Preterm					
Below range <4mL	928 (26.4%)†	706 (19.1%)†	1782 (54.2%)†	1154 (28.4%)†	
In range 4–6 mL	2213 (62.9%)	2618 (70.7%)	1204 (36.6%)	2483 (61.1%)	
Above range >6 mL	380 (10.8%)	379 (10.23%)	305 (9.3%)	428 (10.5%)	
Inflations total	3521	3703	3291	4065	14 580
Total inflations					30 239

*p=0.002.
†p<0.001

DISCUSSION

The results from this study in a group of experienced NICU clinicians showed that using the Juno monitor significantly improved face mask leak and the targeted ventilation delivery in each manikin model using both resuscitation device types (table 2) and (table 3). The use of an RFM during resuscitation to directly measure delivered volumes could allow first responders to safely adjust PIP for both TPR and SIB throughout the resuscitation enabling the target Vte to be consistently achieved. The significant reduction in the frequency of below target range Vte (table 1) if seen in human studies has the potential to reduce volutrauma and atelectotrauma.[19] The ability to dynamically adjust the PIP during resuscitation as a proxy measure for delivered volume is limited when using TPR[20 21] compared with SIB (with manometer fitted). Less experienced first responders using TPR systems may not factor in the need to increase PIP settings, given a slow-responding patient when awaiting more experienced resuscitators to arrive and assist.

The limitations of this study are as follows: (1) generalisation to human studies may not show similar findings, more research is required to demonstrate the value of RFMs in training staff; (2) no subjects were in the 'first responder' experience level, we speculate a greater benefit with first responder use; (3) no user adjustments of PIP when using

Table 2 Inflation count and percentage of leak measured within leak indicator categories by ventilation device, manikin type and Juno monitor display (blinded or unblinded)

	T-piece resuscitator			Self-inflating bag		
	Blinded	Unblinded	Adjusted OR	Blinded	Unblinded	Adjusted OR
Term						
Green	2376 (63.5%)	3151 (83.8%)	Ref 95% CI	3403 (83.0%)	3594 (88.5%)	Ref 95% CI
Orange	484 (12.9%)	374 (9.9%)	−1.9 (−2.2 to −1.7)	338 (8.3%)	319 (7.8%)	−0.9 (−1.1 to −0.7)
Red	880 (23.5%)	234 (6.2%)*	−4.9 (−5.6 to −4.12)	358 (8.7%)	148 (3.6%)*	−3.1 (−3.5 to −2.8)
Inflations	3740	3759		4099	4061	
Preterm						
Green	2284 (64.9%)	3215 (86.8%)	Ref 95% CI	1861 (56.5%)	3435 (84.5%)	Ref 95% CI
Orange	411 (11.7%)	215 (5.8%)	−1.0 (−1.1 to −0.8)	747 (22.7%)	338 (8.3%)	−1.4 (−1.6 to −1.3)
Red	826 (23.5%)	273 (7.4%)	−1.5 (−1.6 to −1.3)	683 (20.8%)	292 (7.2%)	−1.5 (−1.6 to −1.3)
Inflations	3521	3703		3291	4065	

Adjusted OR referent (ref) group green mask leak with 95% CI.
*p<0.001.

Table 3 ANOVA repeated measures adjusted means for leak and deflation tidal volume (Vte) by ventilation device, manikin type and Juno monitor display (blinded or unblinded) with 95% CI

	T-piece resuscitator		Self-inflating bag	
	Blinded	Unblinded	Blinded	Unblinded
Term				
Vte (mL)	20.3 (20.2 to 20.5)	23.2 (23.0 to 23.4)	29.4 (29.2 to 29.7)	28.3 (28.1 to 28.6)
Leak (%)	29.9 (29.3 to 30.6)	16.4 (15.7 to 17.1)	15.8 (15.3 to 16.3)	10.5 (10.0 to 11.0)
Preterm				
Vte (mL)	4.6 (4.6 to 4.7)	5.0 (4.9 to 5.1)	3.7 (3.7 to 3.8)	4.6 (4.5 to 4.6)
Leak (%)	33.1 (32.4 to 33.7)	18.4 (17.7 to 19.0)	38.0 (37.4 to 38.7)	22.6 (22.1 to 23.2)

ANOVA, analysis of variance.

TPR to increase tidal volumes (figure 2) leading to low values, whereas with SIB the volume was adjusted dynamically by squeeze distance. Contributing to this could have also been the lung compliance of the manikins used not being anatomically correct.[4 22] It was not possible to tell if subjects used the tidal volume icon range or displayed volume as we did not use video recordings. The apparent ambiguity in instructions occurred as the study was designed to enrol an equal number of midwives as first responders; however, this was not possible during the COVID-19 pandemic. As with most manikin studies, the duration of PPV measured was brief. Sicker newborns often require a more prolonged duration of PPV. We speculate that fatigue and distraction may worsen mask leak and performance in this situation, highlighting the need for dynamic monitoring. There were statistically significant but small differences in predicted mean tidal volumes within the accuracy tolerance of RFM's pneumotach. This is explained by our overall low leak values in our experienced subjects and that the impact on reduced Vte occurred mostly with leak values >60% (figure 2).

Current International Liaison Committee on Resuscitation (ILCOR) consensus on the use of RFM is based on devices not commercially available[6–8] and are complex systems with GUIs more suited to intensive care unit and anaesthetic domains than birthing environments where unexpected resuscitation is common. First responders have less experience than neonatal staff who may take valuable minutes to arrive on the scene. Even brief periods of over-ventilation can injure the preterm fetal lung and brain.[19 23 24] Relying on subjective assessment of chest wall movement may result in considerable variation in tidal volumes with under-ventilation and over-ventilation.

The latest ILCOR statement on RFMs does not recommend their routine use during resuscitation.[10] The consensus of science knowledge gaps on the key research questions of the role of RFM use during newborn resuscitation includes assessment of improving targeted ventilation and defining problematic average mask leak in general resuscitation delivery which our study provides insight.

This study shows that experienced resuscitators with prior extensive training and competency in using the Juno monitor significantly improved mask seal and targeted ventilation in both extreme preterm and term manikin models. A study of 50 first responders is currently underway. Further research examining clinicians' experiences on the use of this monitor and the duration of skill improvements is underway. The first-in-human safety study of the clinical monitor version (Nemo) has recently been completed.[25]

CONCLUSION

A new and novel in-line RFM (Juno) displaying mask leak and deflation volume significantly reduced mask leak in a group of experienced resuscitators and reduced the number of high leak inflations in both term and preterm manikin models when used with SIB and TPR systems.

Contributors MBT contributed to study design, data collection, data and statistical analysis, and writing of the manuscript. MBT is guarantor. MH contributed to data and statistical analysis and writing of manuscript. MB and MC contributed to prototype 'Juno' monitor development and construction, data collection and review of manuscript. SM (PhD candidate), KL, AP and MC contributed to data collection, manuscript writing, construction and review.

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Competing interests The ResusRight is a startup company founded by MBT, MH, MCrott and M B to commercialise the prototype Juno monitor studied. MT is an unpaid medical consultant for the ResusRight and a minor share holder. MH is an unpaid engineering consultant for the ResusRight and a minor share holder. MCrott is a director and chief technical officer for ResusRight and is a shareholder. MB is a director chief executive officer for ResusRight and is a shareholder.

Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by Sydney Children's Hospital Network Ethics Committee ID 2019/ETH13537. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request.

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