Relationship between applied face mask force and mask leak during simulated neonatal ventilation: a randomised simulation study

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ABSTRACT

Objective Assess the relationship between applied face mask force and leak during simulated ventilation using different ventilating devices and mask holds.

Design Randomised cross-over simulation study.

Setting Quiet, non-clinical room in children's hospital.

Participants Twenty-four experienced neonatal healthcare providers.

Interventions Ventilate a manikin for 2 min per trial, each with three trial conditions: self-inflating bag (SIB) with one-hand hold, T-piece with one-hand hold, T-piece with two-hand hold.

Main outcome measures Applied force (newtons (N)) measured under the head and at four locations on the manikin's face (nasal bridge, mentum, left and right zygomatic arches), force asymmetry applied to the mask rim, and mask leak.

Results Under-head force was greatest using the SIB with one-hand hold (mean (SD) 20.53 (5.87) N) and least using the T-piece with one-hand hold (mean (SD) 17.58 (6.11) N). While mask leak was reduced with increasing force, leak-free ventilation was achieved by some participants in all trial conditions with low (<10 N) under-head force. Force asymmetry on the manikin's face was similar using a one-hand hold compared with a two-hand hold. With both holds, forces were greater on the side of the face corresponding to the operator's non-dominant hand.

Conclusion Applied force and leak varied between devices and mask holds. Force asymmetry was present with both mask holds. Leak-free ventilation could be achieved with small forces using either an SIB or T-piece and either mask hold. Force feedback during training may improve the effectiveness and safety of neonatal ventilation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Effective neonatal face mask ventilation is a difficult skill to acquire and maintain.
⇒ Leak around the mask is a common problem.
⇒ The forces applied to a neonatal manikin during simulated ventilation vary by device, mask and user expertise.

WHAT THIS STUDY ADDS

⇒ During simulated mask ventilation, force applied to the head varies based on device type and mask hold and can be used as a strategy to decrease leak; however, leak-free ventilation can be achieved with small applied force using either device or hold.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ These data support the use of applied force as a metric for evaluating technique and providing feedback when teaching neonatal face mask ventilation.

INTRODUCTION

Assisted ventilation is the single most important step in the resuscitation of newborn infants.[1] Effective face mask ventilation requires proper mask placement to create a seal over the infant's nose and mouth. Clinicians must carefully apply force to the face mask. Too much force could cause injury, obstruct the airway or increase operator fatigue. Too little force may result in leak around the mask rim.[2] Previous work has investigated the effect of mask type, device type and mask hold strategy on ventilation parameters.[3–6] Shah *et al*[3] compared mask holds when ventilating premature newborns and found a reduction in leak when using a two-hand hold compared with a one-hand hold. Others have measured applied forces during neonatal ventilation in both simulation[7] and clinical settings.[8] van Vonderen *et al*[7] demonstrated widely varying force applied to the head during simulated neonatal ventilation with a T-piece resuscitator and a self-inflating bag (SIB) but were unable to identify a significant difference between devices. Kuypers *et al*[8] found that greater forces applied to the face mask correlated to an increased risk of apnoea and bradycardia among premature newborns (<32 weeks' gestation). This relationship could be attributed to the activation of receptors connected to the trigeminal nerve, inducing a trigeminocardiac reflex.[9]

Our previous work characterised forces applied to the face and head of a neonatal manikin when clinicians of varying expertise delivered simulated ventilation with different devices and masks.[10] We found that clinicians applied greater under-head forces when using an SIB compared with a T-piece resuscitator and when using an anatomic mask compared with a round mask. Novice and experienced clinicians applied similar amounts of overall force, but experienced clinicians applied force more symmetrically. The present study builds on our previous work, with the goal of evaluating relationships between applied forces, devices, mask holds and mask leak during simulated positive pressure ventilation (PPV).

MATERIALS/SUBJECTS AND METHODS

Healthcare professionals (HCPs) were eligible to participate if they had completed the American Academy of Pediatrics' Neonatal Resuscitation Program (NRP) training within the past 2 years. Participants were recruited from Neonatal Intensive Care Unit staff at C.S. Mott Children's Hospital at the University of Michigan (Ann Arbor, Michigan, USA) between September and December 2023.

Participants completed three sequential 2 min trials of simulated ventilation using a high-fidelity SimNewB manikin (Laerdal Medical, Stavanger, Norway). For each trial, participants were assigned a ventilation device and mask hold and were instructed to ventilate the manikin following the method described in the American Academy of Pediatrics' Neonatal Resuscitation Program (NRP) 8th edition textbook.[1] All trials were completed using a neonatal size anatomic inflated-rim mask (Ambu, Ballerup, Denmark). The ventilation devices were the NeoPuff T-piece resuscitator (Fisher Paykel, Auckland, New Zealand) and the 500 mL self-inflating bag (SIB) with attached manometer (Mercury Medical, Clearwater, Florida, USA). The three trials consisted of the following combinations: SIB with a one-hand C-E hold, T-piece with a one-hand C-E hold and T-piece with a two-hand C-E hold. During the T-piece two-hand hold trials, the participant held the mask while the researcher occluded the T-piece valve. The same researcher performed T-piece valve occlusion for all participants. Because we felt that the researcher operating the bag had too much potential influence on applied forces and mask leak, we elected not to perform a two-hand hold trial with the SIB. The order in which the trials were completed was randomised with complete counterbalancing, with each sequence of conditions appearing four times. Pairwise t-tests were used to confirm that force and ventilation metrics did not significantly change between trials. Participants rested for 3 min between each trial.

Applied forces were recorded at four locations on the manikin's face (mentum, nasal bridge, left and right zygomatic arches) using ultra-thin microforce sensors (SingleTact, PPS UK Limited, Glasgow, UK), and total compressive force applied to the head was measured using a calibrated load cell (Sparkfun Electronics, Niwot, Colorado, USA) concealed from view. As in our previous study,[10] forces (newtons (N); 1 n=102 gram-force) were continuously measured at 20 Hz using a microcontroller and custom data collection script, and initial values from each force sensor at resting state were recorded and subtracted from the time series such that all sensors had a zero datum when unloaded. Airflow rate and ventilation parameters were measured using a wireless respiratory function monitor (RFM) (Monivent, Gothenburg, Sweden). As recommended by the NRP, the T-piece was preset to 10 L/min, peak pressure 25 cmH_2O, and PEEP 5 cmH_2O. Trials were performed on a dedicated Resuscitation Quality Improvement cart (RQI Partners, Dallas, Texas, USA) in a quiet, non-clinical setting within the hospital. Participants were aware that force and ventilation parameters were being measured. The integrated manometer was visible to participants during ventilation trials, but the RFM data were not.

Ventilation data were parsed by breath using a custom analysis script, and applied forces were averaged over each breath. Leak is represented as a percent and was calculated as the difference between the inspired and expired tidal volume, divided by the inspired tidal volume.[11] Under-head force was parsed into 10 N ranges for categorical analysis and post hoc t-tests. A linear mixed effects model was fit to characterise leak at the face mask, with trial condition and under-head force as predictor variables.

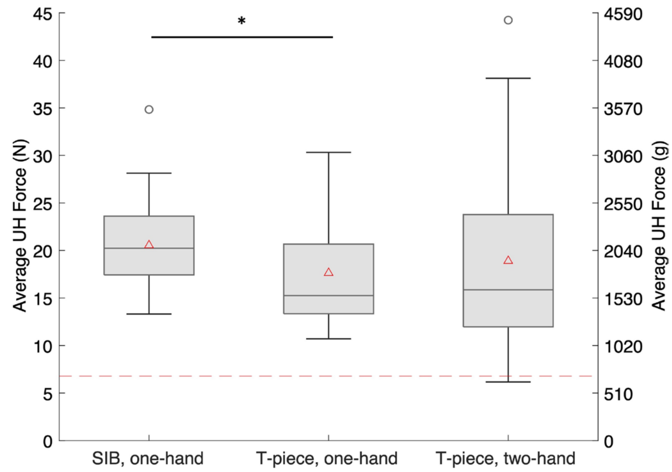

Figure 1 Under-head (UH) force by condition. Box plot displays one data point per person per trial, for a total of 72 datapoints (24 points per box), with red triangles representing the group mean. Asterisk indicates statistical significance between groups, as supported by pairwise t-tests. The red dotted line (6.78 N) indicates the 32 mm Hg pressure injury threshold, calculated by determining the equivalent amount of force distributed over the manikin's occiput contact area (15.90 cm^2).

Force asymmetry was calculated as the difference between the left and right zygomatic arch divided by the sum of the left and right zygomatic arch for each set of data points, such that the force difference is represented as a ratio to the total force applied in the left-right direction. To account for the difference in hand dominance and the effect on mask-holding hand, the sign of the asymmetry values was negated for left-handed participants, resulting in dominant/non-dominant force asymmetry values. Friedman's test was used to assess the effect of trial condition on dominant/non-dominant force asymmetry. An analysis of variance (ANOVA) model was used to assess the relationship between force asymmetry, trial condition and leak. Data are presented as mean (SD) for normally distributed data and median (IQR) for skewed distributions. Pairwise t-tests were conducted for datapoints within a trial and data averaged across each trial, and independent t-tests were used to compare data from each breath. Statistical analyses were performed with MATLAB 2022 (MathWorks, Natick, Massachusetts, USA).

RESULTS

Twenty-four neonatal HCPs participated, including neonatology fellows, attending physicians, respiratory therapists and advanced practice nurses. Two participants reported 1–2 years of experience, two participants reported 3–4 years, three participants reported 5–6 years, and 17 participants reported 6+ years of experience. Force measured under the head varied by trial condition (figure 1). Forces were smallest using the T-piece resuscitator with one-hand hold (mean (SD) 17.58 (6.11) N) and largest using the SIB with one-hand hold (mean (SD) 20.53 (5.87) N). Forces measured with the T-piece resuscitator and two-hand hold (mean (SD) 17.78 (7.71) N) were not different from the other two trial conditions. A logarithmic transformation was applied to the face force sensor data prior to analysis. There was no significant difference in dominant/non-dominant force asymmetry measured on the face between trial conditions (figure 2). Using the one-hand hold, all participants held the mask with their non-dominant hand, referred to here as

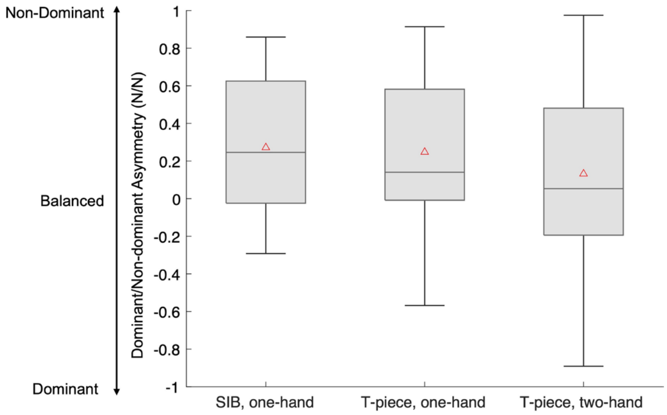

Figure 2 Force asymmetry measured at the patient-mask interface grouped by condition (72 datapoints represented, one per subject for each condition). Dominant/non-dominant asymmetry is represented as a ratio of the difference of force at the left and right zygomatic arch sensors to the total force applied in the left-right directions. Asymmetry direction is labelled based on the participant's dominant and non-dominant hand, where the non-dominant hand was the mask-holding hand in the one-hand conditions. Red triangles indicate the mean value within each group. SIB, self-inflating bag.

the mask-holding hand. A higher force on the zygomatic arch that corresponded with the participant's non-dominant, mask-holding hand was found in all trial conditions, including the two-hand hold (table 1), indicating that participants continued to exert more force with the hand they used for the one-hand hold when performing the two-hand hold.

Across all trial conditions, zero leak was achieved in all force ranges (figure 3), indicating that participants could achieve leak-free ventilation with small (<10 N) under-head force using any studied method. When using the T-piece with one-hand hold, the leak was reduced as applied under-head force incrementally increased (table 2). Leak was also reduced with an increase in applied force using the T-piece and two-hand hold up to the 20–40 N range, at which leak did not change. For the SIB with one-hand hold, leak was similar between 0 and 30 N of applied force (mean (SD) 32.10 (30.1)%) and was reduced with greater than 30N of applied force (mean (SD) 12.96 (10.1)%) (table 2). The ANOVA model revealed an interaction effect between trial condition and force asymmetry on the mask leak. However, in post hoc analysis, we found no linear relationship or monotonic trend showing correlation between asymmetry and leak.

DISCUSSION

The objective of this study was to assess the relationships between applied forces and mask leak when using different ventilation devices and mask hold techniques. We found the T-piece resuscitator resulted in less under-head force compared with the SIB, but under-head force was similar between the one-hand and two-hand hold. Although mask leak tended to decrease with increasing applied force, participants were able to achieve leak-free ventilation using low (<10 N) applied force in all trial conditions. Facial sensors showed that participants applied force asymmetrically to the manikin's face, with greater force applied by the participant's non-dominant hand using either the one-hand or two-hand hold. No clear linear or monotonic relationship was observed between force asymmetry, trial condition and mask leak, highlighting the nuance and variability of face mask placement strategy.

Overall, we found that participants applied less under-head force with a T-piece compared with an SIB. This is consistent with our previous findings[10] and similar to the trend observed by van Vonderen.[7] Focusing on the T-piece trials, we found no difference in the under-head force applied with a one-hand or two-hand hold. The magnitude of the under-head forces was greater in the present study compared with our previous study, which could be attributed to the participants' awareness that leak was an outcome being measured.

The relationship between applied force and leak varied with ventilation device and mask hold. An inverse relationship emerged for the T-piece resuscitator one-hand hold, indicating that increasing applied force decreased mask leak. The same relationship was found for the T-piece with two-hand hold for applied forces ranging between 0 and 30 N. Once the applied force exceeded 30 N, the leak did not change. Overall, the T-piece two-hand hold trial resulted in the greatest proportion of breaths in the lowest force range (<10 N) when compared with the other two trial conditions. When using the SIB with one-hand hold, leak was unchanged between 0 and 30 N with a reduction in leak after applying 30–40 N force. In all three trial conditions, participants were able to achieve leak-free ventilation in all force ranges, indicating that low leak can be achieved with less than 10 N force applied to the manikin's head. These results illustrate that effective ventilation with low applied force is possible with appropriate technique but suggest that increasing applied force is a strategy that HCPs may use to mitigate leak when ventilating a neonatal manikin with a one-hand hold.

Surprisingly, dominant/non-dominant force asymmetry was similar across all three trial conditions, indicating that use of a two-hand mask hold during simulated ventilation did not decrease asymmetry of applied forces. Larger applied forces were measured at the zygomatic arch corresponding with the participant's non-dominant hand for all trial conditions, even when using a two-hand hold. These results suggest that it may be helpful to assess force directionality during ventilation training to emphasise proper mask hold strategy, especially

Table 1 Relationship between mask-holding hand and forces measured at each zygomatic arch for each condition

Condition	Mask-holding hand	N (people)	n (datapoints within comparison)	Left zygomatic arch (median (IQR))	Right zygomatic arch (median (IQR))	Pairwise t-test p value	Cohen's d
SIB, one-hand	Left	22	1324	0.656 (0.50–1.12) N	0.603 (0.40–0.81) N	<0.0001	0.60
	Right	2	251	0.585 (0.25–0.65) N	1.067 (0.95–1.84) N	<0.0001	2.52
T-piece, one-hand	Left	22	1136	0.807 (0.50–1.22) N	0.558 (0.37–0.71) N	<0.0001	0.78
	Right	2	124	0.548 (0.49–0.79) N	1.881 (0.67–1.99) N	<0.0001	1.27
T-piece, two-hand	Left	22	1299	0.883 (0.54–6.34) N	0.780 (0.66–1.03) N	<0.0001	0.57
	Right	2	125	0.627 (0.57–0.71) N	1.079 (1.03–1.25) N	<0.0001	3.43

SIB, self-inflating bag.

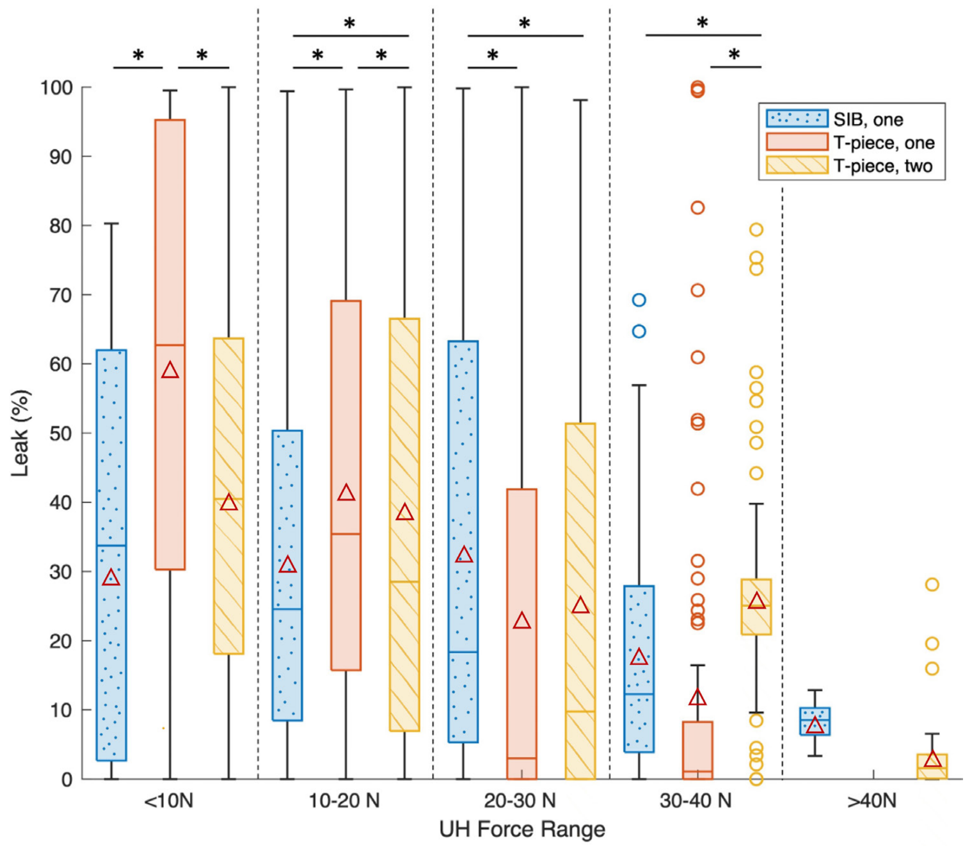

Figure 3 Leak versus measured under-head (UH) force per condition (5005 breath data points represented). Asterisks indicate statistical significance between conditions within a given force range, and red triangles represent the mean within each group. Summary statistics and relationships describing statistical significance within a given condition across force ranges are described in-text and in table 2. SIB, self-inflating bag.

when performing the two-hand hold. This analysis did not find a clear relationship between force asymmetry and mask leak. Future studies should test a larger sample size and expand the force measurement contact points at the patient-mask interface to further assess any correlation between force asymmetry and ventilation parameters.

Table 2 UH force range and corresponding leak for each condition

Condition	UH force range (N)	n (breaths)	Leak percentage (mean (SD)) (%)
SIB, one-hand hold	<10	27	29.57 (28.3)
	10–20	1004	32.89 (28.5)
	20–30	856	33.84 (33.4)
	30–40	101	17.63 (17.3)
	>40	11	8.29 (2.9)
T-piece, one-hand hold	<10	63	59.67 (32.4)
	10–20	966	41.92 (29.8)
	20–30	341	23.85 (33.8)
	30–40	73	12.57 (25.2)
	>40	0	–
T-piece, two-hand hold	<10	264	39.43 (32.4)
	10–20	763	38.11 (33.7)
	20–30	544	25.95 (31.7)
	30–40	71	26.81 (15.8)
	>40	19	4.67 (7.8)

SIB, self-inflating bag; UH, under-head.

For context, we converted the applied force to pressure (mmHg) by dividing the measured force (N) by the sensor surface area when the head was in a neutral position (occiput contact area: 15.90 cm^2) and compared it to a commonly referenced threshold (32 mm Hg) for preventing soft tissue injury in adults and older children.[12] We found that the average under-head pressure for all trial conditions exceeded the reference threshold (T-piece, one-hand: 82.93 mm Hg; T-piece, two-hand: 83.88 mm Hg; SIB, one-hand: 96.85 mm Hg). As noted above, training with the manikin may encourage clinicians using a one-hand hold to use >30 N force to mitigate leak. These values raise concern that if the under-head pressures exerted during training with a manikin were sustained during actual neonatal resuscitations, they could lead to injury, especially given the lower mean arterial and capillary blood pressure in newborn infants.[13] Additionally, excessive forces in clinical practice could induce a trigeminocardiac reflex, resulting in apnoea and bradycardia.[9] This excess force and potential for injury highlights the need for training equipment to accurately reflect the clinical environment. Similar to surgical simulation, there is a risk that training with a manikin that lacks haptic fidelity will lead to the development of bad habits and negative transfer to the clinical setting where the learner might apply excessive forces that can be difficult to untrain.[14] Providing force feedback to clinicians during training may mitigate the risk of negative transfer and lead to a reduction in applied force and force asymmetry in the clinical setting.

The use of a manikin introduces some limitations. Although a high-fidelity neonatal manikin was used, the mechanical properties of the manikin's head and skin elasticity differ from an infant, which could result in discrepancies between our measurements and the force applied in a clinical setting. However, we believe these measurements are relevant because they reflect the forces used during training, which could result in unsafe techniques transferred to the clinical setting. Participants were aware of the force measurements, which could have influenced them to apply less force than in a typical training scenario. However, this possibility indicates that participants may be applying even greater forces when unmonitored than those characterised in this study. Administering ventilation to an infant in a clinical environment involves reacting to unexpected movements and dynamic health conditions, which are not captured while ventilating the manikin in quiet room and static state. Finally, force sensors on the manikin's face were placed at four fixed locations, limiting our ability to capture all contact points at the patient interface, which could provide additional information about mask placement. Future studies could investigate the effect of mask placement strategy on applied forces with a modified force measurement apparatus.

In summary, we found that experienced clinicians applied greater force on the side of the face mask corresponding to the typical mask-holding hand, even when using a two-hand mask hold. Although increasing force tended to decrease mask leak when using a one-hand hold, increasing under-head force to decrease leak raises concerns for potential tissue injury if transferred to the clinical setting. Moreover, leak-free ventilation could be achieved while applying <10 N of force with either a T-piece or SIB and either hold. These results suggest that incorporating applied force as a training feedback metric could help clinicians learn to achieve effective ventilation with less force, less asymmetry and contribute to safer ventilation technique. We plan future studies to assess the effects of real-time applied force feedback on ventilation parameters.

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Contributors All authors have actively contributed. JH: Conceptualised and designed the study, collected and analysed data, wrote the first draft of the manuscript, and reviewed and revised the manuscript. GW and LS: Conceptualised and designed the study, supervised the project, and reviewed and revised the manuscript. All authors approved the final manuscript and accept full responsibility for the work. LS is the guarantor.

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Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by University of Michigan Institutional Review Board (HUM #00236465). Participants gave informed consent to participate in the study before taking part.

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