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Clinical paper

Exerted force on the face mask in preterm infants at birth is associated with apnoea and bradycardia

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Abstract

Background: During stabilisation of preterm infants at birth, a face mask is used to provide respiratory support. However, application of these masks may activate cutaneous stretch receptors of the trigeminal nerve, causing apnoea and bradycardia. This study investigated the amount of force exerted on the face mask during non-invasive ventilation of preterm infants at birth and whether the amount of exerted force is associated with apnoea and bradycardia.

Methods: A prospective observational study was performed in preterm infants born <32 weeks of gestation who were stabilised at birth. During the first 10 minutes of respiratory support, we measured breathing and heart rate as well as the amount of force exerted on a face mask using a custom-made pressure sensor placed on top of the face mask.

Results: Thirty infants were included (median (IQR) gestational age(GA) 28^{+3} (27^{+0}–30^{+0}) weeks, birthweight 1104 (878–1275) grams). The median exerted force measured was 297 (198–377) grams, ranging from 0 to 1455 grams. Significantly more force was exerted on the face mask during positive pressure ventilation when compared to CPAP (410 (256–556) vs 286 (190–373) grams, $p = 0.009$).

In a binary logistic regression model, higher forces were associated with an increased risk of apnoea (OR = 1.607 (1.556–1.661), $p < 0.001$) and bradycardia (OR = 1.140 (1.102–1.180), $p < 0.001$) during the first 10 minutes of respiratory support at birth.

Conclusion: During mask ventilation, the median exerted force on a face mask was 297 grams with a maximum of 1455 grams. Higher exerted forces were associated apnoea and bradycardia during the first 10 minutes of respiratory support at birth.

Keywords: Preterm infants, Force, Face mask, Apnoea, Bradycardia

Introduction

Preterm infants often require respiratory support at birth because their breathing is insufficient to meet their metabolic needs. In order to provide non-invasive ventilation (e.g. continuous positive airway pressure (CPAP) or positive pressure ventilation (PPV)), a face mask is applied over the infant's nose and mouth using adequate force to ensure mask seal and prevent mask leak.[1] A manikin study showed that the force exerted on the face during mask ventilation varied between 606 and 3717 grams in different caregivers.[2] Application of this force may activate cutaneous stretch receptors of the trigeminal nerve, causing a cessation of breathing (apnoea) and a reduction in heart rate leading to bradycardia. This is also known as the trigeminocardiac reflex (TCR).[1,3,4] We recently demonstrated that the application of the face mask was followed by apnoea in 54% of preterm infants, and in 77% of preterm infants <28 weeks.[3] Although the occurrence of apnoea induced by the TCR could depend on the amount of manual force applied to the infant's face, it is currently unknown how much force is used by caregivers during mask ventilation of preterm infants.

The aim of this prospective observational study was to investigate the amount of force exerted on the face mask during non-invasive ventilation of preterm infants at birth and to determine whether the amount of exerted force is associated with apnoea and bradycardia.

Methods

A prospective observational study was performed at the Leiden University Medical Centre (LUMC) from February to September

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2022 to investigate the amount of force applied to the face masks during mask ventilation at birth. To continuously monitor the amount of force applied to the face mask, a custom-made sensor (Sens-O) was developed.

Pressure sensor: Sens-O

The Sens-O consisted of three parts: a silicone tire, a short piece of tubing and a pressure sensor. The silicon tire was made out of two silicone casts that were glued together with silicone glue (inner diameter of 16.5 mm, outer diameter of 35, 42 or 50 mm (depending on mask size) and a height of 6 mm). Each silicone cast consisted of 60 shore silicone that was reinforced with embedded PMMA plates to ensure even distribution of the force exerted on the Sens-O. In addition, the tire had a torus shape with a flat surface to create sufficient grip (Fig. 1).

The tubing was clamped within the opening of the silicone tire at one end and connected to the pressure sensor (MPXV5050DP, a Piezo resistive Transducer) at the other end. When force was exerted on the silicon tire, the internal pressure of the tire increased, which was measured by the sensor at the end of the tubing. The pressure sensor was connected to an Arduino micro-controller (Ivrea, Italy) where the data was processed. To ensure a user-friendly set up, a box was made with an air input for the pressure sensor and a data output for the Arduino.

Prior to birth, the Arduino was coupled to our Respiratory Function Monitor (part of standard care during neonatal resuscitation; Advanced Life Diagnostics and Applied Biosignals, Weener, Germany) via USB, where the measured force was recorded synchronously with the cardiorespiratory measurements of the infant. In contrast to the cardiorespiratory data, the measured force was not visible for the caregiver during neonatal resuscitation. The first and/or last pressure values measured were used to calibrate the sensor. The pressure values were then converted into weights by using a validated custom-made transfer function that was unique for each Sens-O.

The Sens-O was available in the sizes XS, S and M as these mask sizes are most often appropriate for preterm infants <32 weeks.[5] The mean absolute percentage error was 6.3%, 3.6% and 11.1% for the different Sens-O sizes, respectively. For safety measures, a manikin study was performed to evaluate the effect of adding the Sens-O to the face mask on mask leak and provided force by the caregiver. No differences were observed in the amount and duration of mask leak or the amount of exerted force on the face mask with and without the Sens-O.

Study protocol

Neonatal stabilisations of preterm infants <32 weeks of gestation were eligible for inclusion. Exclusion criteria were: (i) the Sens-O was not used or available (e.g. emergency setting), (ii) no storage of force measurements or (iii) the Sens-O had a leak resulting in unreliable results.

All caregivers were trained in using the Sens-O during neonatal stabilisation and provided informed consent to use the collected force measurements. Parents were approached for consent in retrospect to collect the respiratory and heart rate data for the first 10 minutes after starting respiratory support in the immediate newborn period. In case of a language barrier or if it was considered inappropriate to approach parents in the immediate newborn period, the infant's data was only used if parents did not use the opt-out procedure implemented at our NICU for data use for retrospective studies.

Prior to birth, the Sens-O was applied on top of the face mask (Neonatal Resuscitation Mask, Fisher & Paykel Healthcare Ltd, Auckland, New Zealand) and connected to the RFM. Standard care was provided in the delivery room following local resuscitation guidelines. A Neopuff™ Infant Resuscitator (Fisher & Paykel Healthcare, Auckland, New Zealand) was used to provide non-invasive respira-

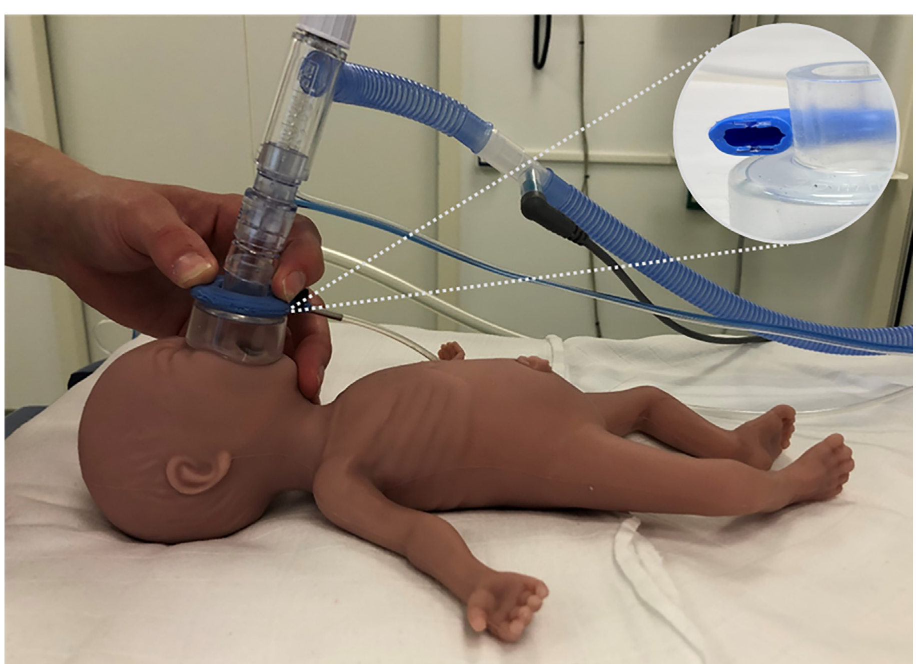

Fig. 1 – Custom made pressure sensor placed on top of a face mask to continuously measure the exerted force of caregivers on the face mask during mask ventilation.

tory support. All gases were heated and humidified. A disposable flow sensor (Avea Varflex Flow transducer; Carefusion, CA, USA) was placed in between the face mask and the T-piece to record respiratory function using the New Life Box (Advanced Life Diagnostics, Weener, Germany) and Polybench physiological software (Applied Biosignals, Weener, Germany). Heart rate (HR) and oxygen saturation (SpO2) were recorded by a Radical-7 Masimo SET pulse oximeter probe (Masimo Corporation, CA, USA) placed around the infant's right hand.

The primary outcome was the amount of force exerted on the face mask during the first 10 minutes of respiratory support after birth. The secondary outcomes were the incidence of apnoea and bradycardia. Spontaneous breathing was determined by using the flow waveforms and when there was some doubt about the waveforms, observations from the video recording were used for confirmation. These indicators of breathing included visible chest excursions, crying or vivid movements of the extremities. Apnoea was defined as the absence of spontaneous breathing for at least 5 seconds and bradycardia as a heart rate <100 bpm.

Collected demographic characteristics were gestational age, birth weight, gender, Apgar score at 1 and 5 min, mode of delivery, use of corticosteroids, multiple birth and type of anaesthesia.

As this was the first observational study investigating the amount of force applied to the face during mask ventilation of preterm infants at birth, there were no pre-existing data available to calculate an appropriate sample size. A study investigating the target sample size for pilot and feasibility studies reported a median sample size of 30 participants per arm in studies with a continuous parameter as the endpoint.[6] Therefore, 30 neonatal stabilisations were included.

The medical ethics committee Leiden Den Haag Delft approved the study protocol (N21140) and issued a statement of no objection for performing this study.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics version 25 (IBM, Chicago, Illinois, 2021). Results are presented as number (%) for dichotomous variables, mean ± SD for normally distributed continuous variables or median (IQR) for non-normally distributed continuous variables. The amount of force exerted was calculated by including a mean force per stabilisation in each analysis. Except for the average and peak forces exerted after initial or subsequent mask applications as they were analysed per mask application. A related samples Wilcoxon Signed Ranks test was used to compare the average amount of force used during CPAP and PPV, and one-hand and two-hand hold. A Mann-Whitney U test was performed to test the difference in forces between 29 initial and 77 subsequent mask applications. A binary logistic regression was used to predict the effect of the exerted force (corrected for the infant's birthweight), time from birth, heart rate or spontaneous breathing, oxygen saturation and type of respiratory support on the risk that infants became apnoeic or bradycardic in the first 10 minutes of respiratory support after birth, respectively. Type of respiratory support was added to this analysis to adjust for the higher forces measured during PPV and the relationship of PPV and apnoea and/or bradycardia (e.g. PPV can cause apnoea/bradycardia or is provided when apnoea/bradycardia is present) A p-value <0.05 was considered significant.

Results

Between February and September 2022, there were 75 eligible neonatal stabilisations <32 weeks of gestation of which 30 were included (Fig. 2). During the majority of stabilisations, a mask size S (67%) was used and the mask ventilation was provided by a junior resident (60%; Table 1). Infants had a median gestational age of 28^{+3} (27^{+0}–30^{+0}) weeks and birthweight of 1104 (878–1275) grams (Table 1).

Exerted force during respiratory support at birth

The median force measured during the first 10 minutes of respiratory support at birth was 297 (198–377) grams with a maximum of 1455 grams. Significantly more force was exerted on the face mask when PPV was given compared to CPAP (410 (256–556) vs 286 (190–373) grams, $p = 0.009$) during the same stabilization. No differences in the amount of exerted force were observed between a one- or two hand mask hold (292 (204–413) vs 321 (163–407), $p = 0.701$) during the same stabilisation. The median force measured after mask application (initial and subsequent mask placement) per stabilisation was 379 (256–483) grams with a peak force within the first 5 seconds after mask application of 436 (317–573) grams. (Table 2).

Exerted force during initial and subsequent mask applications

In total, 106 mask applications were analysed (29 initial applications and 77 subsequent applications. No significant differences were observed in peak forces measured in the first 5 seconds after mask application (437 (345–681) vs 394 (260–610) grams, $p = 0.171$) or average exerted force during the 30 seconds after mask application between initial and subsequent mask placements (376 (278–498) vs 322 (252–493) grams, $p = 0.391$). However, in 60% (9/22) of the stabilisations in which mask re-application was observed the peak forces measured after subsequent mask placements were lower compared to initial mask placement during the same stabilisation.

Exerted force and its' association with apnoea and bradycardia

A binary logistic regression was performed to evaluate the effect of time, gestational age, heart rate, oxygen saturation, exerted force and type of NIV on the likelihood that infants would become apnoeic in the first 10 minutes of respiratory support after birth. The logistic regression model was statistically significant, $\chi^2(6) = 7223.390$, $p < 0.001$. The model explained 59.6% (Nagelkerke R^2) of the variance in the occurrence of apnoea and correctly classified 94.5% of the cases. Higher exerted forces (OR = 1.607 (1.556–1.661), $p < 0.001$) as well as time from birth, lower gestational age, lower heart rates, lower oxygen saturations and PPV as respiratory support were associated with an increased incidence of apnoea during the first 10 minutes of respiratory support at birth (Table 3A).

The amount of force (corrected and uncorrected for birthweight) exerted on the face mask was significantly higher during periods of apnoea compared to periods of spontaneous breathing (corrected: 396 (257–610) vs 243 (147–387) grams/kg, $p < 0.001$; uncorrected: 409 (232–557) vs 283 (175–385) grams, $p < 0.001$).

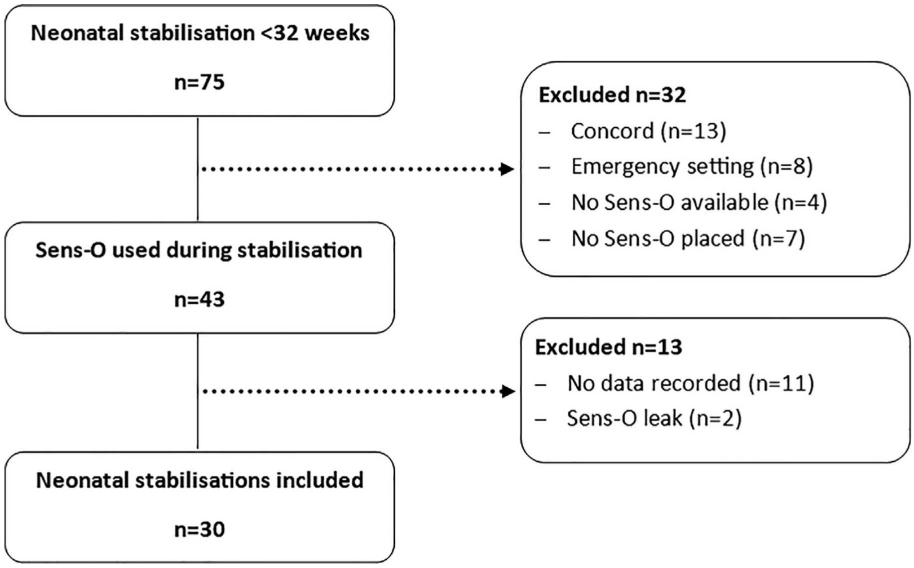

Fig. 2 – Flow chart inclusions.

Table 1 – Resuscitations' and patients' characteristics.

	Resuscitations *N* = 30		Infants *N* = 30
Grade of resuscitator		Gestational age (weeks)	28^{+3} (27^{+0}–30^{+0})
Junior resident, *n* (%)	18 (60)	Birth weight (grams)	1104 (878–1275)
Resident, *n* (%)	6 (20)	Male gender, *n* (%)	14 (47)
Fellow, *n* (%)	1 (3)	Multiples, *n* (%)	13 (43)
Physician assistant, *n* (%)	3 (10)	Complete course of antenatal steroids, *n* (%)	17 (57)
Neonatologist, *n* (%)	2 (7)	Caesarean section, *n* (%)	17 (57)
First mask size used		General anaesthesia, *n* (%)	4 (13)
Size XS, *n* (%)	7 (23)	Time till cord clamping (s)	60 (40–175)
Size S, *n* (%)	20 (67)	Apgar score 1 min	6 (4–6)
Size M, *n* (%)	3 (10)	Apgar score 5 min	8 (7–8)
		Apgar score 10 min	9 (8–9)
		Positive pressure ventilation given, *n* (%)	13 (43)

Table 2 – Exerted force measurements during the first 10 minutes of respiratory support.

	Resuscitators *N* = 30	
	Median (IQR)	Highest value measured
Force	297 (198–377)	1455
Force during CPAP	286 (190–373)	1374
Force during PPV	410 (256–556)	1455
Force during one-handed mask hold	292 (204–413)	1455
Force during two-handed mask hold	321 (163–407)	974
Force after mask placement	379 (256–483)	1455
Peak force after mask placement	437 (317–573)	1455

Force measurements are noted in grams. Force after mask placement (initial and subsequent mask placement) is calculated over the first 30 seconds after mask application and peak force is the maximum force measured in the first 5 seconds after mask application.

A binary logistic regression was performed to evaluate the effect of time, gestational age, oxygen saturation, apnoea, exerted force and type of NIV on the likelihood that infants would be bradycardic in the first 10 minutes of respiratory support after birth. The logistic regression model was statistically significant, $\chi^2(6) = 6480.433$, $p < 0.001$. The model explained 55.7% (Nagelkerke R^2) of the

Table 3 – Binary logistic regression analyses. Binary logistic regression analysis to evaluate the effect of time, gestational age, heart rate or breathing (respectively), oxygen saturation, exerted force and type of respiratory support on apnoea (A) or bradycardia (B) during the first 10 minutes of respiratory support at birth.

(A)

		95% CI Odds Ratio		
	Odds ratio	Lower	Upper	*p*-value
Time in sec	0.999	0.999	1.000	<0.001
Gestational age in weeks	0.684	0.660	0.708	<0.001
Heart rate (bpm)	0.983	0.981	0.985	<0.001
Oxygen saturation (%)	0.950	0.946	0.953	<0.001
Exerted force (corrected for birthweight) in 100 grams	**1.607**	**1.556**	**1.661**	**<0.001**
Type of NIV (CPAP = 1, PPV = 2)	2.676	2.319	3.088	<0.001
Note: $\chi^2(6) = 7679.390$, $p < 0.001$, R^2 (Nagelkerke): 0.596, correctly classified in 94.5% of the cases.				

(B)

		95% CI Odds Ratio		
	Odds ratio	Lower	Upper	*p*-value
Time in sec	0.995	0.994	0.995	<0.001
Gestational age in weeks	0.923	0.891	0.956	<0.001
Oxygen saturation (%)	0.951	0.948	0.954	<0.001
Apnoea	2.483	2.106	2.928	<0.001
Exerted force (corrected for birthweight) in 100 grams	**1.140**	**1.102**	**1.180**	**<0.001**
Type of NIV (CPAP=1, PPV=2)	2.125	1.853	2.437	<0.001
Note: $\chi^2(6) = 6480.433$, $p < 0.001$. R^2 (Nagelkerke): 0.557, correctly classified in 94.5% of the cases.				

variance in the occurrence of bradycardia and correctly classified 94.5% of the cases. Higher exerted forces (OR = 1.140 (1.102–1.180), $p < 0.001$) as well as time from birth, lower gestational age, lower oxygen saturations, apnoea and PPV as respiratory support were associated with an increased incidence of bradycardia during the first 10 minutes of respiratory support at birth (Table 3B).

The amount of force (corrected and uncorrected for birthweight) exerted on the face mask was significantly higher during periods of bradycardia compared to periods without bradycardia (corrected: 352 (229–558) vs 262 (147–401) grams/kg, $p < 0.001$; uncorrected: 333 (215–519) vs 273 (170–383) grams, $p < 0.001$).

Discussion

This study evaluated the amount of force that is exerted by the caregiver on the face mask during the application of mask ventilation in preterm infants <32 weeks at birth. The median amount of force exerted during face mask ventilation was 297 grams with a maximum of 1455 grams and significantly higher forces were exerted on the face mask during PPV. The application of higher forces on the face mask were, among other factors, associated with the occurrence of apnoea and/or bradycardia during the first 10 minutes of respiratory support at birth. Caregivers should be aware that the forces they exert on the face mask in order to acquire an adequate mask seal for respiratory support in preterm infants might compromise the breathing they intend to support.

The median and range of force observed in this study was considerably lower than those in a previous manikin study,[2] which reported a range of 606 – 3717 g. This difference can be explained by multiple factors: (i) experimental vs clinical setting, (ii) term manikin vs preterm infant and (iii) force measurement underneath the head vs on the face mask. The latter factor is probably the biggest contributor as an electronic scale was placed underneath the head of the manikin without the caregiver's knowledge. This measured all forces applied to the head of the infant (not the mask) and to the bed surrounding the head. As our study only measured the force applied to the face mask, it provides a more representative and accurate measurement of the exerted force on the face mask.

In this study, the measured peak forces after subsequent mask placement were in 60% of the stabilisations lower when compared to the peak forces after initial mask placement in the same stabilisation. As higher forces are associated with apnoea and bradycardia, this finding is consistent with the observations of two retrospective studies[7,8] which reported that apnoea and bradycardia were more common in response to initial compared with subsequent mask applications in preterm and term infants. However, these previous studies considered that the effect of re-application was caused by habituation (de-sensitisation) of the facial receptors, whereas our findings indicate that it was just as likely due to the application of less force on re-application of the face mask.

As the amount of force exerted on the face mask is negatively associated with breathing and heart rate, it is highly likely that application of a face mask during respiratory support at birth stimulates the cutaneous facial receptors and that the amount of force applied then determines to what extent the TCR is provoked. This is also consistent with previous studies demonstrating different breathing rates following placement of a lightweight cardboard ring or a face mask (rim) on the infant's face suggesting that it may be necessary to exceed a threshold before provoking a TCR response.[9] This threshold will likely vary between infants as this reflex is clearly modified by a number of factors including lower gestational age, lower heart rates and lower oxygen saturations, all of which contribute to a higher risk of apnoea.

When infants become apnoeic during mask ventilation, it might be helpful to evaluate whether caregivers are applying too much force on the face mask. A visual cue for this could be the decolourisation of the skin around the face mask. Caregivers could then consider to momentarily remove the face mask and re-apply it more gently. Nonetheless, we were unable to define a cut-off value for too much force as multiple factors influenced whether an infant became apnoeic. However, gently applying a face mask while achieving sufficient mask seal and applying not too much force on the face mask is a delicate balance and addressing this issue during resuscitation training might be valuable.

As caregivers placed the Sens-O on the face mask when preparing the resuscitation table, it is possible that it reminded them to be more vigilant about the amount of force they exert when applying the face mask. Therefore, the measured forces might be an underestimation of the force normally exerted. However, as stabilisations of preterm infants can be stressful and caregivers have to focus on many different things, we expect this awareness to disappear from the moment the infant is placed on the resuscitation table. Therefore, we consider that this non-blinded component of the study had limited impact on our results. In addition, some caregivers applied the face mask while holding the flow sensor and exert force on the infant's face via the flow sensor instead of exerting force directly on the mask. In these cases, no representative force upon the infant's face is measured, which explains why in some instances the measured force applied to the face mask was 0 grams. As it is hard to distinguish between force applied directly to the mask or (partly) via the flow sensor, we decided to include all measurement and accepted a possible underestimation of the total amount of exerted force to the infant's face. In this study, we were able to measure the amount of exerted force applied to the face mask and an association with apnoea and bradycardia, however, we were unable to establish causation. Experimental studies would be necessary to investigate this.

Conclusion

The median measured force exerted on a face mask during respiratory support of preterm infants at birth was 207 grams with a maximum of 1455 grams. Higher exerted forces were associated with apnoea and bradycardia, which might be induced by the TCR. This finding suggests that there might be a threshold to exceed for provoking a TCR. However, as infants with a lower gestational age, lower heart rates, lower oxygen saturations were at higher risk of apnoea, this reflex is clearly modified by other factors as well. Caregivers should be vigilant in applying a face mask and be aware that the amount of force exerted on the face mask may compromise the breathing they intend to support.

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Author statement

KK: co-conceived the study, conducted the study, collected, analysed and interpreted the data, wrote the first draft of the manuscript and approved the final version of the manuscript. SC, JD, RV, SH: data interpretation, reviewed and edited the manuscript and approved the final version of the manuscript. AtP: co-conceived the study, supervised the study, interpreted the data, reviewed and edited the first draft of the manuscript and approved the final version. All authors agree to be accountable for all aspects of the work.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: 'K.L.A.M. Kuypers is the recipient of an unrestricted research grant from Fisher & Paykel Healthcare Limited; they had no role or influence in study design nor in the collection, analysis, and interpretation of data, writing of the report and decision to submit the paper for publication.'.

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