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Clinical paper

Tidal volumes and pressures delivered by the NeoPuff T-piece resuscitator during resuscitation of term newborns

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Abstract

Aim: T-piece resuscitators are commonly used for respiratory support during newborn resuscitation. This study aimed to describe delivered pressures and tidal volumes when resuscitating term newborns immediately after birth, using the NeoPuff T-piece resuscitator.

Method: Observational study from June 2019 through March 2021 at Stavanger University Hospital, Norway, including term newborns ventilated with a T-piece resuscitator after birth, with consent to participate. Ventilation parameters of the first 100 inflations from each newborn were recorded by respiration monitors and divided into an early (inflation 1–20) and a late (inflation 21–100) phase.

Results: Of the 7730 newborns born, 232 term newborns received positive pressure ventilation. Of these, 129 newborns were included. In the early and the late phase, the median (interquartile range) peak inflating pressure was 30 (28–31) and 30 (27–31) mbar, and tidal volume was 4.5 (1.6–7.8) and 5.7 (2.2–9.8) ml/kg, respectively. Increased inflation times were associated with an increase in volume before plateauing at an inflation time of 0.41 s in the early phase and 0.50 s in the late phase. Inflation rates exceeding 32 per minute in the early phase and 41 per minute in the late phase were associated with lower tidal volumes.

Conclusion: There was a substantial variation in tidal volumes despite a relatively stable peak inflating pressure. Delivered tidal volumes were at the lower end of the recommended range. Our results indicate that an inflation time of approximately 0.5 s and rates around 30–40 per minute are associated with the highest delivered tidal volumes.

Keywords: Newborn resuscitation, T-piece resuscitator, NeoPuff, Positive pressure ventilation, Tidal volume

Introduction

The transition from foetal to newborn life involves aeration of liquid-filled lungs and onset of air breathing.[1] While most newborns make this transition spontaneously, 4–8% need positive pressure ventilation (PPV) after birth.[2–4] PPV may be administered by a self-inflating bag, a flow-inflating bag, or a flow-driven T-piece resuscitator. Although there has been insufficient evidence to recommend one device over another,[5] flow driven T-piece resuscitators have become increasingly popular in high- and middle resource settings,

Abbreviations: PPV, Positive Pressure Ventilation, PIP, Peak Inflating Pressure, PEEP, Positive End-expiratory Pressure, FRC, Functional Residual Capacity

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in large part due to their advantage of delivering a steady peak inflating pressure (PIP) and positive end-expiratory pressure (PEEP).[6–8] A recent International Liaison Committee on Resuscitation (ILCOR) summary statement suggests the use of a T-piece resuscitator over the use of a self-inflating bag in newborns receiving PPV at birth.[9] However, while the majority of newborns in need of PPV at birth are term born (gestational age $\geq$ 37 weeks),[3–4,10] the studies supporting this recommendation are mostly limited to premature newborns.[11–14]

The key to successful PPV is to provide sufficient inflation pressures to create functional residual capacity (FRC) and to deliver adequate tidal volumes to ensure gas exchange.[15] When ventilating term newborns, the American Heart Association (AHA) recommends an initial PIP of 20–25 cm H_2O, whereas the European Resuscitation Council (ERC) and the Australian and New Zealand Committee on Resuscitation (ANZCOR) recommend an initial PIP of 30 cm H_2O.[16–18] When using a T-piece resuscitator, the initial PIP is set accordingly. However, airway resistance, lung compliance, the newborn's tone and respiratory effort will vary substantially during the first minutes of PPV. Thus, a single set PIP is unlikely to result in adequate tidal volumes in all neonates. A small study including 20 preterm newborns receiving PPV in the delivery room, showed that a PIP of approximately 30 cmH_2O resulted in tidal volumes between 0 and 30 ml/kg, implying a weak correlation between PIP and delivered tidal volumes.[19] Resuscitation guidelines suggest a target tidal volume between 5 and 8 ml/kg during delivery room resuscitation,[16] although recent studies have suggested that higher tidal volumes may be warranted.[20–21] A recent study from Tanzania, including more than 800 term newborns ventilated with a self-inflating bag without PEEP, suggests that pressures of 37 cmH_2O may sometimes be required in apnoeic newborns to achieve tidal volumes within the target range.[22] In that study, inflation times were approximately 0.45 s. However, longer inflation times and lower inflation rates may ensure tidal volumes within the target range despite a lower PIP.

In this prospective observational study, we placed a flow- and pressure sensor between the facemask and the T-piece resuscitator to measure ventilation parameters during the first minutes of PPV of term newborns. The aim was to assess delivered PIP, PEEP, tidal volume, inflation time and rate, and to study the association between PIP, inflation time, inflation rate, and the achieved tidal volumes.

Methods

Setting

The study was conducted between 1st of June 2019 and 31st of March 2021 at Stavanger University Hospital, Norway. It is the only hospital in the region with delivery and newborn services and has approximately 4300 annual deliveries. Our department practises delayed cord clamping. Depressed newborns who do not respond to drying and stimulation, will have their cord clamped and moved to a centrally placed resuscitation bay for treatment. All resuscitation bays are equipped with a T-piece resuscitator (NeoPuff, Fisher&Paykel Healthcare, Auckland, New Zealand) and self-inflating bag (Upright, Laerdal Medial, Stavanger, Norway).[4] At our hospital, NeoPuff is the primary device for PPV of newborns. The airflow is set at 8 litres per minute, PIP at 30 cmH_20 and PEEP at 5 cmH_2O, in accordance with European guidelines.[16] Settings are checked by midwives once every 8-hour shift, and by the resuscitation team on arrival at the resuscitation bay. The resuscitation team consists of the midwife, nurse assistant, and a paediatric resident. A consultant neonatologist may be called upon in cases of severe asphyxia. All staff involved in newborn resuscitation undergo regular neonatal resuscitation skill and simulation training, including PPV using NeoPuff.

Inclusion- and exclusion criteria

Women were invited to consent to their newborn's participation in the study at routine ultrasound screening in pregnancy week 20 or when admitted for labour. Only newborns born at term who received PPV by NeoPuff within the first 5 min after birth were eligible for inclusion. Newborns ventilated with a self-inflating bag and newborns with congenital malformations were excluded.

Data collection and analysis

Video cameras with motion sensors were mounted on the resuscitation bays, recording all newborn resuscitations. The video recordings were used to assess the newborn's respiratory effort at initiation of PPV (apnoeic, gasping or severe retractions). A respiratory function monitor (Laerdal Global Health, Stavanger, Norway) with a hot-wire anemometer flow sensor (MIM Gmbh, Krugzell, Germany) and a piezo resistive pressure sensor (MPXV5010, Freescale Semiconductor Inc, Austin, TX) was connected between the T-piece and the facemask. The respiratory function monitor has a lever formed to hold the T-piece and mask when not in use, and lifting up the T-piece would initiate recording. For each inflation, the respiratory function monitor measured and recorded PIP and PEEP (in mbar; 1 mbar equals 1.02 cmH_20), tidal volume (defined as expiratory volume in ml), leak (defined as difference between inflated and expiratory volume divided by inflated volume, presented as a percentage), dynamic lung compliance (ml/mbar), inflation time, and instant inflation rate (60 divided by the time interval between current and previous inflation). No visual feedback on ventilation parameters was displayed to the healthcare providers. Patient characteristics were extracted from the electronic medical records. To prevent over-representation of data from newborns who were ventilated for a longer period, only the first 100 inflations from each newborn were

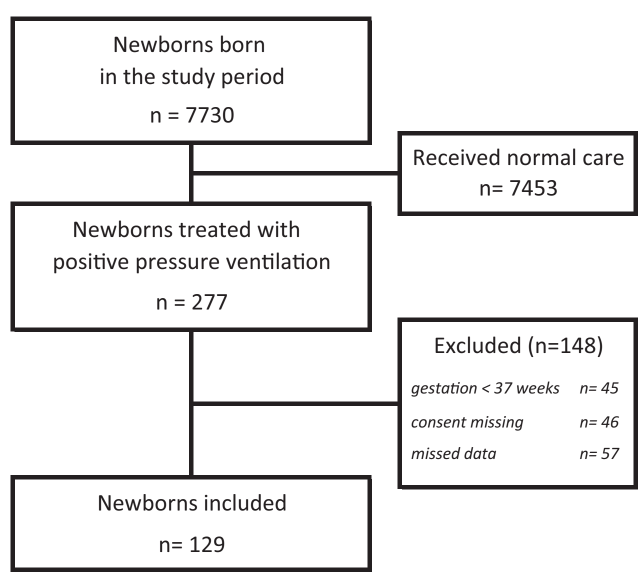

Fig. 1 – Flow diagram of inclusion.

Table 1 – Clinical characteristics of 129 included term newborns receiving positive pressure ventilation at birth.

	n = 129
Male gender	74 (57%)
Weight (g)	3647 (609)
Gestational age (weeks)	40 (1)
Mode of Delivery	
Vaginal delivery	86 (67%)
Caesarean section	43 (33%)
Apgar score at	
1 min	4 (3–6)
5 min	8 (6–9)
10 min	9 (7–10)
Umbilical cord blood values*	
arterial pH	7.19 (7.11–7.25)
arterial base deficit	5.4 (3.9–6.3)
venous pH	7.32 (7.25–7.36)
venous base deficit	4.8 (3.4–6.1)

Gender and mode of delivery presented as n (%), weight and gestational age as mean (SD), Apgar scores and umbilical cord blood values as median (IQR).
* n = 114.

included. We defined the first 20 inflations as the early phase of liquid clearance and establishment of FRC, and the following 80 inflations as the late phase of lung gas exchange with predominantly established FRC.[15,22]

Statistics

Data were analysed, and charts drawn, using R (Version 4.1.1., R Development Core Team, Vienna, Austria). Mann-Whitney U-test was used to compare continuous variables between the early and late phases.

Generalized Estimation Equations (GEE) (R-package: geepack v.1.3–2) were applied to model dynamics of PIP, PEEP, mask leak, lung compliance and tidal volume. Inflation number was included as the only predictor variable. First-order autoregressive covariance structure (AR(1)) was chosen to represent the within-subject dependencies for all models.

Further, we applied GEE to study the relationships between the tidal volume as the outcome variable and inflation rate, inflation time and PIP measured at the same inflation as predictors. We included inflation rates between 20 and 90 per minute, inflation times between 0.2 and 1.4 s, and inflation pressures between 18 and 34 mbar, thus excluding inflations incompatible with ventilation techniques appropriate in this setting. Visual inspection of the smoothing estimates of all models suggested a linear relationship with a sudden change in slope. Thus, for each GEE models we applied segmented regression (breakpoint) analysis, searching for a single breakpoint using quasi-likelihood information criterion (QIC),[23] the estimated breakpoints were presented together with the regression coefficients before and after.

P-values < 0.05 were considered statistically significant. Continuous variables are presented as median (Interquartile range (IQR)) unless otherwise stated.

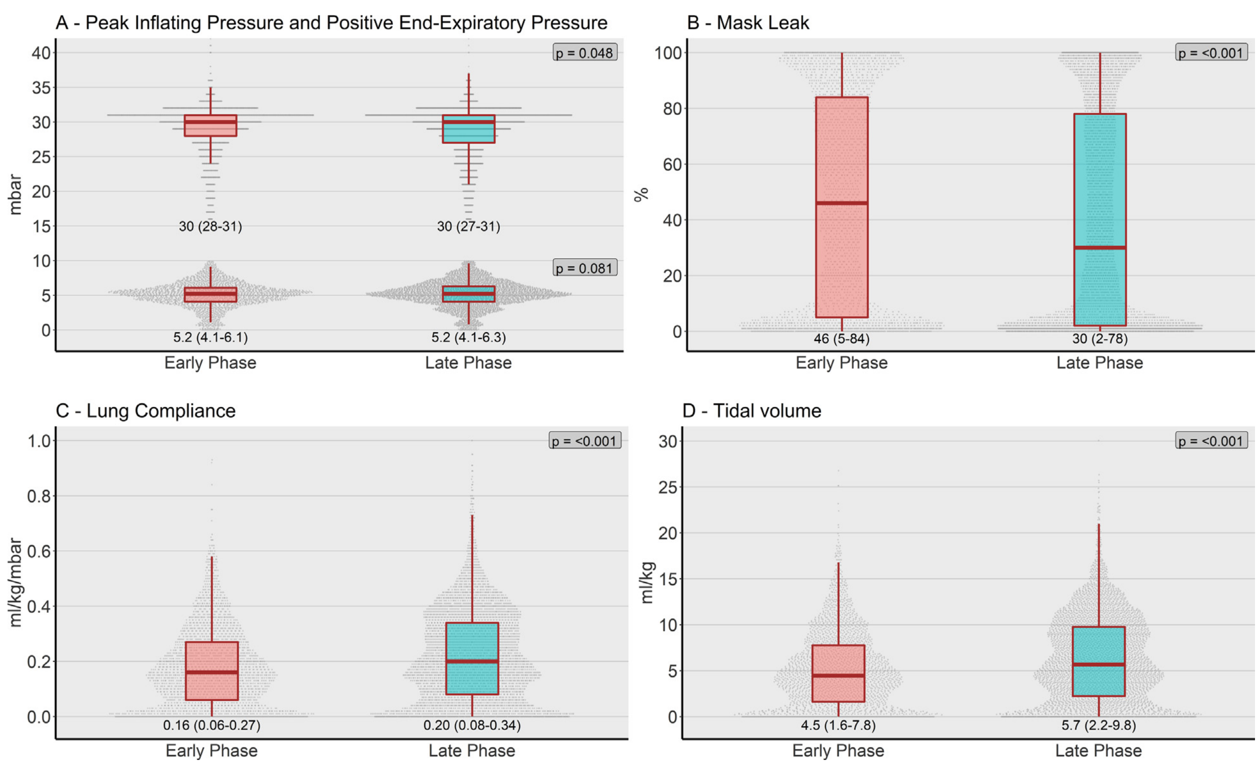

Fig. 2 – Swarmplots and boxplots of A) Peak inflating pressures and Positive End-Expiratory pressures, (B) Mask leak, (C) Lung compliance, and (D) Tidal volumes of the first 100 inflations during positive pressure ventilation of 129 term newborns after birth, and divided into an early phase (first 20 inflations, n = 2393) and a late phase (inflation 21–100, n = 4148). The swarmplots displays the distribution of individual observations on the y-scale. The boxes extend from the 25th to the 75th percentile; the horizontal line within the box denote median values; vertical extending lines denote range excluding outliers. Mann-Whitney U-test was used to compare variables between the early and late phase.

Results

Of 7730 newborns delivered during the study period, 277 (3.6%) received PPV after birth. Of these, 232 were born ≥ 37 weeks of gestation and were eligible for inclusion. We excluded 103 newborns due to missing parental consent (n = 46) or missing ventilation data (n = 57). The remaining 129 newborns were included in the study (Fig. 1), resulting in a total of 6541 inflations for analysis, 2393 in the early phase and 4148 in the late phase. The clinical characteristics of the 129 included newborns are presented in Table 1.

Five resuscitations were not video recorded due to technical issues. In the other 124 resuscitations, 109 (88%) of the newborns were apnoeic upon arrival at the resuscitation table whereas 15 (12%) newborns had insufficient respiratory efforts (i.e. gasping or severe retractions) prior to initiation of PPV. The median (IQR) ventilation time was 86 (49–130) s, and each newborn received 47 (25–72) inflations. The inflation rate was 43 (34–53) per minute and the inflation time was 0.58 (0.45–0.74) s.

Graphical representation of distributions of the tidal volume, mask leak, dynamic lung compliance, PIP and PEEP for the early and late phases are shown in Fig. 2. There was a substantial variation in tidal volumes, despite a relatively stable PIP. Median tidal volume did not reach the recommended range in the early phase and was in the lower end of the recommended range in the late phase. Mask leak decreased and the lung compliance increased from the early to the late phase.

The tidal volumes, mask leak, dynamic lung compliance, PIP and PEEP of the first 20 inflations are shown in Fig. 3. Throughout the early phase, the delivered PIP and PEEP were stable, the lung compliance and tidal volumes slowly increased, and the mask leak decreased.

The impact of PIP, inflation times and inflation rates on delivered tidal volumes are shown in Fig. 4 and Table 2. The tidal volumes increased with increasing PIP up to 30 mbar in both phases and decreased with higher PIP. Increased inflation times were associated with a rapid increase in volume before plateauing at an inflation time of 0.41 s in the early phase and 0.50 s in the late phase. Inflation rates exceeding 32 per minute in the early phase and 41 per minute in the late phase were associated with lower tidal volumes.

Discussion

This single centre study is the first to describe delivered tidal volumes and applied pressures from a flow-driven T-piece resuscitator during ventilation of term newborns. We found substantial variation in delivered tidal volumes despite a relatively stable delivery of PIP. The mask leak was high, and the lung compliance was generally low.

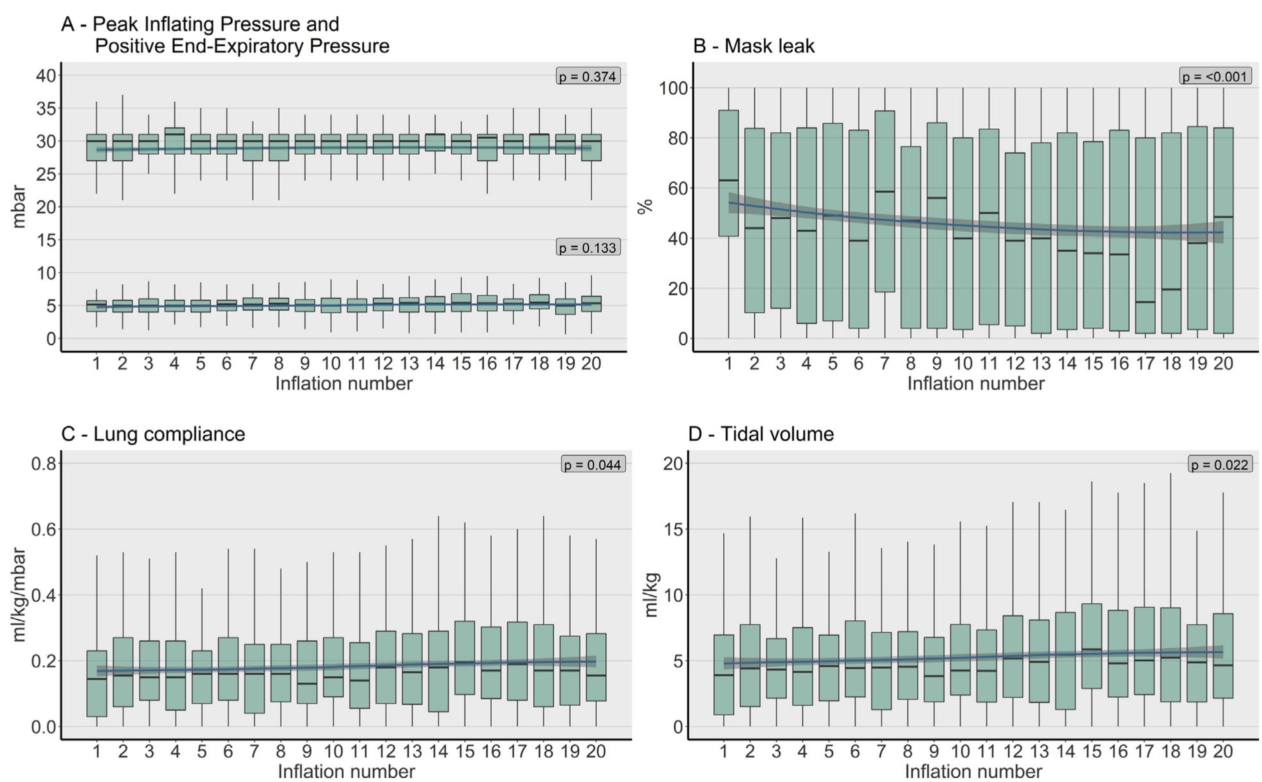

Fig. 3 – Boxplots of (A) Peak inflating pressures and Positive End-Expiratory pressures, (B) Mask leak, (C) Lung compliance, and (D) Tidal volumes for the 20 first inflations during positive pressure ventilation of 129 term newborns after birth. The boxes extend from the 25th to the 75th percentile; the horizontal line within the box denote median values; vertical extending lines denote range excluding outliers. The blue line represents the mean value throughout all 20 inflations, smoothed through local regression (Local Estimated Scatterplot Smoothing) with the grey band representing a 95% confidence interval. P-values are calculated using generalized estimation equations.

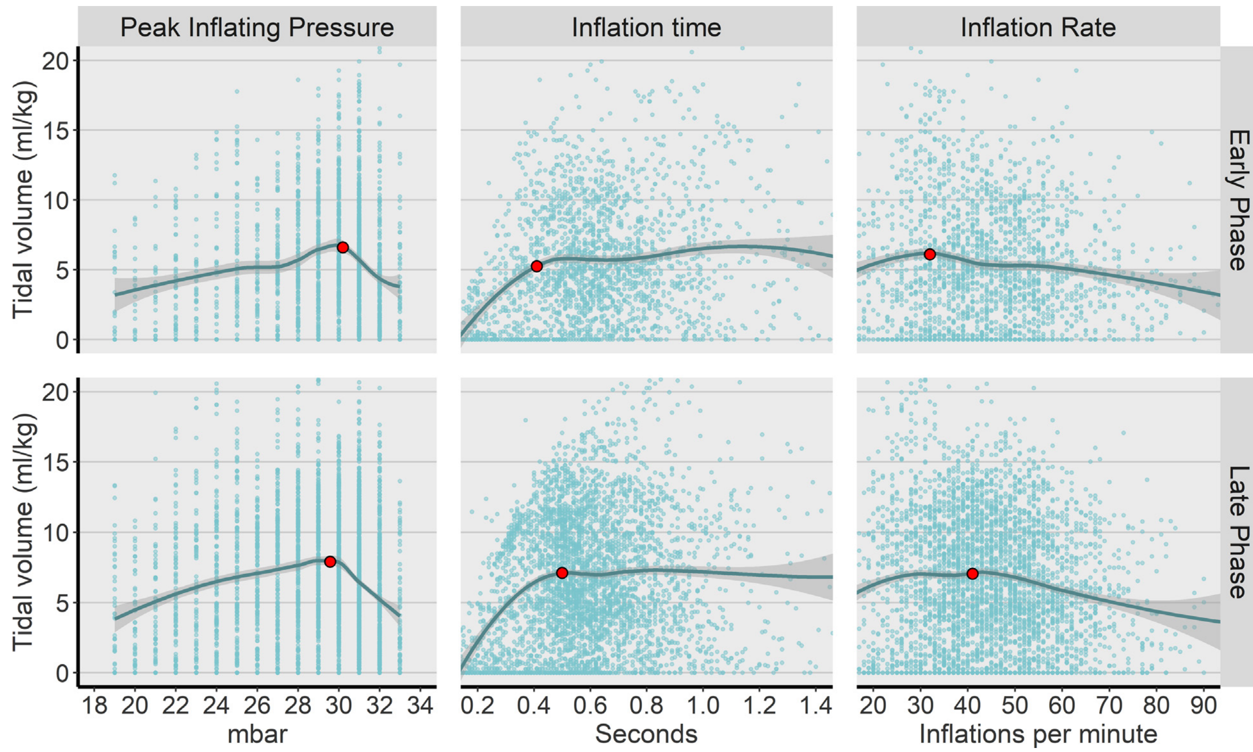

Fig. 4 – Scatterplots illustrating the association between peak inflating pressure, inflation time, and inflation rate on delivered tidal volumes from positive pressure ventilation of 129 term newborns after birth. The blue line represents the mean value smoothed through local regression (Local Estimated Scatterplot Smoothing) with the grey band representing 95% confidence intervals. The red dots represent breakpoints from the segmented regression analysis (Table 2).

Table 2 – Breakpoint- and generalized estimating equations (GEE) analyses of the relationship between tidal volume and different variables when ventilating newborns at term using a T-piece resuscitator in the early (first 20 inflations) and late (inflation 21–100) phases.

Variable	Break point	Before Breakpoint		After Breakpoint	
		Regression coefficient	p-value	Regression coefficient	p-value
Early Phase					
Peak Inflating Pressure (mbar)	30.20	0.27 (0.15; 0.40)	**<0.001**	−1.03 (−1.71; −0.34)	**0.03**
Inflation time (s)	0.41	12.76 (3.50; 22.02)	**0.007**	3.65 (2.12; 5.18)	**<0.001**
Inflation rate (inflations/min)	32.00	0.03 (−0.16; 0.21)	0.77	−0.04 (−0.06; −0.01)	**<0.001**
Late Phase					
Peak Inflating Pressure (mbar)	29.58	0.39 (0.31; 0.48)	**<0.001**	−0.96 (−1.38; −0.54)	**<0.001**
Inflation time (s)	0.50	11.00 (7.26; 14.74)	**<0.001**	2.30 (0.51; 4.09)	**0.01**
Inflation rate (inflations/min)	41.00	−0.03 (−0.08; 0.03)	0.36	−0.04 (−0.06; −0.02)	**<0.001**

The tidal volumes achieved when ventilating compromised newborns with a T-piece resuscitator at the recommended settings of 30/5 cmH_2O did not reach target tidal volumes during the early phase. However, this is a phase where a proportion of the inflated air will remain in the lungs generating FRC. This is visualized by the gradual increase in tidal volumes throughout the early phase (Fig. 3). Hence, the measured (expired) tidal volumes are likely to underestimate delivered tidal volumes. In this phase, the provision of a sufficient and steady pressure may be more important than reaching a target volume.

In the following (late) phase, gas exchange is the primary aim of PPV, as well as maintaining FRC by preventing liquid from re-entering the alveoli. Spontaneously breathing term newborns are reported to achieve a tidal volume between 4–6 ml/kg in the first minutes after birth.[24–25] In apneic newborns, higher tidal volumes may be required to establish and maintain FRC.[26] A study of 215 near-term and term newborns receiving PPV in the delivery room found that tidal volumes above 6 ml/kg were necessary to increase heart rate, and that tidal volumes between 9 and 10 ml/kg ensured the largest increase in heart rate, as a marker of successful lung aeriation.[20] Another more recent study of 434 late preterm and term newborns found that an inflation rate of 30 per minute and tidal volumes of 10–14 ml/kg were associated with the highest CO_2 clearance.[21] However, high tidal volumes are associated with brain damage in preterm newborns,[27] and animal studies have shown that tidal volumes between 8 and 15 ml/kg may induce lung damage.[28–29] Thus, optimal tidal volumes during PPV in the delivery room remain unknown. Guidelines suggest a target tidal volume between 5–8 ml/kg during newborn resuscitation.[16] In our study, the set PIP of 30 cmH2O resulted in tidal volumes at the lower end of this range.

Of some concern is the substantial variation in delivered tidal volumes and the large proportion of inflations falling outside the recommended target range (Fig. 2). This variety probably has several explanations. Although there was an evident variation in mask leak, the T-piece resuscitator managed to maintain a stable PIP, which should reduce the impact from mask leak on delivered tidal volumes. Hence, we speculate that variation in airway resistance and lung compliance, due to the dynamic course of establishing FRC, may have a greater impact on delivered volume. In addition, maintaining an open airway during repetitive stimulation and handling of the newborns in the time of ventilation is challenging. Finally, as the newborn responds to interventions, the tone and spontaneous respiratory effort will increase. In this aspect, a fixed inflation pressure seems less appropriate. Our findings are consistent with previous studies of mask ventilation at birth.[11,19,21–22,30–35] This illustrates the challenge of estimating delivered tidal volumes, and more importantly, detecting if the newborn receives any tidal volume at all.

Our results clearly demonstrate that steady PIP is no guarantee of adequate ventilation, weakening one of the assumed advantages of T-piece resuscitators. Modern newborn ventilation strategies endorse volume-targeted ventilation,[36] and we see no reason why this should not apply to delivery room resuscitation. Chest rise is an inaccurate method of assessing tidal volume.[19,30] The use of respiratory monitors to provide immediate feedback may improve the quality of PPV in the delivery room.[31,35,37]

As air enters the lungs during inflation, intrathoracic pressure increases until it reaches the inflating pressure, and airflow ceases. The breakpoint analysis (Table 2 and Fig. 4) implies that this equilibrium is reached at an inflation time of approximately 0.5 s, and that longer inflation times will not affect tidal volumes notably. Breakpoint analysis also suggests that tidal volumes start to decrease with inflation rates higher than 30–40 per minute, probably due to reduced inflation times. The recommended inflation times and rates differ between guidelines. ERC and AHA recommend inflation times < 1 second, whereas ANZCOR recommend 0.3–0.5 s.[16–18] ERC suggests inflation rates of 30 per minute, whereas AHA and ANZCOR recommend 40–60 per minute. Our results suggest that when FRC is established (late phase), an inflation time of approximately 0.5 s and inflation rates between 30 and 40 per minute ensure the highest tidal volumes at current set-PIP of 30 cmH_20 (Fig. 4).

Tidal volumes increase with increasing PIP up to 30 mbar (Table 2 and Fig. 3). This breakpoint at 30 mbar is probably reflecting the T-piece resuscitators' set value of 30 cm H_20. We occasionally recorded PIPs clearly exceeding the set-PIP (Fig. 2). These recordings typically corresponded to a negative flow (Supplemental material: Extract of a ventilation monitor report), indicating manipulation of the mask or a newborn respiratory effort. Hence, we would expect a different breakpoint with a different set-PIP, and the association between tidal volumes and PIP for pressures exceeding 30 mbar must be interpreted with caution.

Limitations

There was a high rate of missing ventilation data due to failed recordings and lack of consent. If the T-piece was not placed on the monitors' lever prior to resuscitation, recordings would not be triggered. This occurred often, but randomly, and should not in our opinion create any bias. Parental consent was primarily obtained at routine ultrasound screening in pregnancy week 20, and missing consent should not result in any important bias. During periods of high mask leakage, some of the exhaled air likely bypassed the flowmeter, leading to an underestimation of tidal volumes and lung compliance. Although apnoeic at initiation of PPV, some newborns may have initiated spontaneous breathing gradually during resuscitation, probably affecting the delivered tidal volumes. This study did not include measurements of heart rate, SpO_2 or CO2, nor did it investigate the newborns response to applied PPV, and therefore cannot conclude on the effectiveness of delivered tidal volumes.

Conclusion

During real newborn resuscitation with a T-piece resuscitator at standard settings of 30/5 cmH2O, the delivered tidal volumes were at the lower end of the recommended range. Our results indicate that with a set-PIP of 30 cmH_20, and when FRC is established, highest tidal volumes are achieved with an inflation time of approximately 0.5 s and inflation rates around 30–40 per minute. There was a substantial variation in tidal volumes, indicating that a steady PIP is no guarantee for adequate ventilation.

Conflicts of Interest

None.

CRediT authorship contribution statement

Peder Aleksander Bjorland: Conceptualization, Methodology, Investigation, Formal analysis, Writing – original draft. **Hege Langli Ersdal:** Conceptualization, Methodology, Writing – review & editing. **Joanna Haynes:** Methodology, Writing – review & editing. **Anastasia Ushakova:** Formal analysis, Writing – review & editing. **Knut Øymar:** Conceptualization, Methodology, Writing – review & editing. **Siren Irene Rettedal:** Conceptualization, Methodology, Supervision, Writing – review & editing.

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The external funding sources had no role in study design, data collection, data analysis, data interpretation, writing of the report, or in the decision to submit the paper for publication. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Ethics and Patient Consent

The study was approved by the regional ethical committee (REKvest 2018/338), and the hospital data protection officer. Written parental consent was obtained prior to inclusion.

Author contribution

PAB, SR, HE and KØ designed the study protocol. PAB and SR practically implemented, supervised and carried out the study and the data collection on site. PAB and AU analysed the ventilation data. All authors participated in the interpretation of the results. PAB drafted the initial manuscript. All authors read, revised and approved the final manuscript.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.resuscitation.2021.12.006.

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